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Approved For Release 2008/08/28 : CIA-RDP86-00735R000100010030-0

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Approved For Release 2008/08/28 : CIA-RDP86-00735R000100010030-0

Friday
January 16, 1981

1/22/81

Part XI

Department of Labor

Occupational Safety and Health
Administration

Hazards Identification; Notice of
Proposed Rulemaking and Public
Hearings

DEPARTMENT OF LABOR**Occupational Safety and Health Administration****29 CFR Part 1910****Hazards Identification; Notice of Public Rulemaking and Public Hearings****AGENCY:** Occupational Safety and Health Administration, Labor.**ACTION:** Notice of proposed rulemaking; notice of public hearings.

SUMMARY: The proposed standard requires employers to identify the hazardous chemicals in their workplaces, and to inform their employees of the identity and nature of the employees' hazardous exposures. OSHA has determined that this standard is necessary because most employees are not aware of the presence of hazardous chemicals in their workplaces, or of the health effects exposure to these hazards may produce. Furthermore, many employers are also unaware of the complete chemical identities and hazards of the chemicals in their workplaces. The proposed standard would alleviate these problems through specific hazard identification and evaluation procedures, labeling requirements, and records preservation. Public hearings are being scheduled to permit interested parties the opportunity to orally present information and data related to the issues raised by this proposed rule.

DATES: Comments must be received on or before April 18, 1981.

Notices of intention to appear at the public hearings must be received on or before May 1, 1981.

The hearings are scheduled as follows:

Date Hearing Will Begin and City

1. May 26, 1981, Washington, D.C.
2. July 7, 1981, Houston, Texas
3. July 21, 1981, Chicago, Illinois
4. August 11, 1981, Philadelphia, Pennsylvania
5. September 1, 1981, San Francisco, California.

ADDRESS: Comments should be submitted, in quadruplicate, to the Docket Officer, Docket H-022, U.S. Department of Labor, Occupational Safety and Health Administration, 200 Constitution Avenue, N.W., Room S-6212, Washington, D.C. 20210; (202) 523-7894.

Notices of intention to appear should be submitted to Mr. Tom Hall, Division of Consumer Affairs, Room N3635, U.S. Department of Labor, Occupational Safety and Health Administration, 200 Constitution Avenue, N.W., Washington, D.C. 20210, (202) 523-8024.

Addresses for the hearing locations will be published in the Federal Register at a later date.

Written comments received and notices of intention to appear will be available for inspection and copying in the Docket Office, Room S6212 at the above address.

FOR FURTHER INFORMATION CONTACT:*Proposal*

Mr. James Foster, Room N3641, Office of Public Affairs, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C., 20210; (202) 523-8151.

Hearings

Mr. Tom Hall, Division of Consumer Affairs, Room N-3635, U.S. Department of Labor, Occupational Safety and Health Administration, 200 Constitution Avenue, N.W., Washington, D.C. 20210, (202) 523-8024.

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Approximately 25 million American workers are currently exposed on the job to chemical or physical hazards. As many as 40 to 50 million Americans (23 percent of the entire U.S. population) may have been exposed to one or more of the hazardous chemicals presently regulated by OSHA at some point during their lifetime (1).^{*} Yet, as indicated in the NIOSH National Occupational Hazards Survey (NOHS) discussed below, workers are generally unaware of the presence of hazardous chemicals in the workplace and of the very real potential that exposure to such chemicals may injure their health. Furthermore, some workers complain that even where they receive information about hazardous chemicals, it is often inaccurate or incomplete.

Thus, workers and their representatives have consistently emphasized in previous OSHA rulemakings the need for OSHA to promulgate a standard for chemical substance identification. The following testimony presented during the OSHA rulemaking hearings on "Access to Employee Exposure and Medical Records," OSHA Docket H-112, is evidence of workers' concerns about a labeling regulation (25).

(A)pproximately 150 new chemicals come into that plant every day, many of them with just trade names, many with just a code number. As I have been investigating, every company uses a different code number * * *

Many times our people are exposed for a month, six weeks or two months before we find out (the chemical identity) * * * then, after we have it evaluated, (the company) will remove it; but the damage is already done.

(Mr. John Mroczkowski, United Steelworkers, Tr. 1189-1190, OSHA Docket H-112.)

(N)ow our employees are rather well-schooled craftsmen. They can recognize hazards if they know what the hazard is. Our basic problem is on a daily exposure we have to work with coolants, lubricants, and the vapors that result from the use therein * * *

^{*}Numerical references are to the References listed in this preamble, *infra*.

The thing we are asking for is a labeling, a chemical labeling of what really is contained in that lubricant or that coolant. And I think we can take it from there. We are not asking for a hell of a lot. But if the men don't know what they are being exposed to on a daily basis, there is nothing they can do about it until years later. And then it is too darn late.

(Mr. Victor Horvath, International Ass'n of Machinists, Tr. 1378, OSHA Docket H-112)

(W)e must reiterate the importance of labeling data * * * without some kind of very efficient labeling data we are absolutely in the dark about many chemicals that are used in our shop.

(Mr. Michael Gaffney, United Autoworkers, Tr. 1325, OSHA Docket H-112)

Without adequate chemical substance identification, millions of workers with routine exposures to hazardous chemical substances are unaware of the hazards posed by these substances; and are thus incapable of protecting themselves or ensuring that their employers provide adequate protection. The need for self-protection is no trivial matter. Workers are exposed to hazardous chemicals both in the workplace and the general environment, making them the greatest involuntary consumers of hazardous chemicals in the nation. And in many cases, exposure in the workplace is far greater than what occurs in the general environment. Consequently, to leave workers ignorant of the hazards they face, without the ability to protect themselves, would be incompatible with OSHA's duty under the Occupational Safety and Health Act of 1970, 29 U.S.C. 651 *et seq.*, to assure every working man and woman in the nation, so far as possible, safe and healthful working conditions.

This lack of an adequate system for the identification and labeling of hazardous substances in the workplace has been, and continues to be, a contributing factor in the occurrence of occupational disease. As the Committee on Government Operations, U.S. House of Representatives concluded in its report, *Chemical Dangers in the Workplace* (Thirty-fourth Report, 1976) (26):

Identifying and controlling toxic substances in the workplace is becoming progressively more difficult as more chemicals, chemical processes, and chemical products are used in industry. Tens of thousands of trade-name products, whose chemical contents are not disclosed, are used daily. Lack of knowledge about exposure hampers the identification of occupationally

caused diseases, illnesses, and deaths and is a major impediment to preventing them.

Dr. Thomas Mancuso, an occupational medicine practitioner for thirty years, addressed the problem of inadequate chemical substance identification at Congressional hearings held in 1976 on control of toxic substances in the workplace (25). Dr. Mancuso stated:

* * * the doctor in practice, if he is to make a medical diagnosis, needs information about the work environment and the specific work exposures, the specific chemicals to which his worker patient was exposed prior to the illness. Basically, this lack of information constitutes the fundamental obstacle to the recognition of causality of an occupational illness and appropriate steps and approaches must be evolved to overcome this fundamental problem.

Dr. Mancuso also indicated that there is a nation-wide lack of recognition of occupationally-related illness, disease, and death by the worker and his family, by the doctor, by the industry and by the government. He further stated:

This stems in general from the fact that for decades the workers, the doctors and society have been predominantly oriented and trained on the infectious causes of disease, due to bacteria and viruses, and there has been a corresponding lack of realization of the impact of the many thousands of chemicals—the microchemicals in the work environment—in the causation of illness, disability, and death.

Similarly, Dr. Daniel Teitelbaum, a practicing occupational toxicologist familiar with the problems of inadequate substance identification in occupational medicine, offered the following testimony at the OSHA hearings on access to records (28):

(W)hen such (chemical identification) information is not provided to a consultant, diagnostic difficulties often occur. Patients usually do not know what materials were used in the course of their employment. Even if they are familiar with the material, they do not know the health effects, the level of their exposure, or the chemistry of the material itself. They are usually unable to provide to me enough information for development of a definitive diagnostic and treatment program. (Tr. 116, OSHA Docket H-112)

To end the disparity between what workers now know and what they should know about potential chemical hazards in the workplace, OSHA is today proposing a comprehensive hazard identification standard which will require employers to communicate two types of basic information to their employees. Under the standard, an employer must inform employees of the precise chemical identity of the hazardous chemicals with which they work. The employer must also warn employees of the particular hazards

posed by chemicals in the workplace, including any applicable precautions to be used when working with hazardous chemicals. This information would be conveyed to the workers by the use of container labels, placards, and material safety data sheets.

The benefit of informing workers of the particular hazards of a chemical is immediate and direct. The need for workers to know the precise chemical identities of the hazardous chemicals with which they work is less direct, but no less important.

Access to the precise chemical identity of hazardous chemicals will substantially improve the ability of workers to participate actively in the promotion of health and safety in the workplace, whether their efforts be individual or combined with the efforts of physicians, unions, or agencies of government concerned with worker health. For example, access to the precise chemical identities of hazardous chemicals will give workers the capability to:

- Provide physicians with exact descriptions of workplace exposures when workers suspect occupational causes of disease or material impairment of bodily functions;
- Complement incomplete information communicated to workers concerning the hazards of workplace chemicals;
- Participate with their employers on an intelligent basis in designing and implementing industrial hygiene precautions and procedures to promote workplace health and safety.

In addition, if a requirement for a substance-employee identification list is included in the finale rule, then workers will be able to:

- Obtain an accurate history of the hazardous chemicals to which a worker might have been exposed in the workplace as an aid in identifying the causes of chronic diseases and diseases with long latency periods;
- Determine, with scientific assistance, any additional adverse effects upon workers that are known to be caused by prolonged exposures to chemicals which have been classified as posing only a moderately acute hazard;
- Determine, with scientific assistance, whether worker exposure to various chemicals results in synergistic adverse effects not attributable to any one chemical.

Without access to precise chemical identity, workers must continue to rely principally upon their employers, and upon the limited resources of OSHA and NIOSH, for protection against injury and disease caused by hazardous chemicals. These resources are inadequate, and to

fulfill its statutory mandate to strive for a safe and healthful workplace for every worker, OSHA must give workers the means to protect themselves.

OSHA realizes that some employers have already made efforts to institute substance identification and labeling practices in their establishments as part of their occupational safety and health programs. However, although they may conform to some industry consensus standard, such as that of ANSI, these programs are not uniformly designed or self-enforced. Also, the use of identification systems is not widespread in industry. Even when a system is in place, the system may be unique only to that establishment, and may not be as comprehensive as would be necessary to be truly effective. These inadequacies were clearly demonstrated by the results of the NIOSH occupational health survey, which is discussed below. As a result, the Committee on Government Operations concluded in its 1976 report that voluntary identification standards were not adequately protecting employees. The report stated (26):

Attempts at self-regulation by the chemical industry have not generated adequate information for buyers and users about toxic chemicals in industrial products. Voluntary labeling guidelines developed by the chemical manufacturing industry are directed primarily to the avoidance of injury from single, accidental exposures and do not address the health hazards caused by chronic low-level exposure to toxic chemical substances.

As a result of their investigations in this regard, the Committee concluded:

We believe that industry self-regulation is preferable to governmental intervention if it can produce the necessary level of safety. To this point, however, self-regulation, although laudable, has not been equal to the task.

Similarly, the provisions contained in the regulations of other Federal agencies and state governments, which are described below, are also not comprehensive in scope. None of the Federal statutes adequately addresses itself to the problems presented by hazardous materials in the workplace environment. While nine of the fifty states have regulations covering labeling in the workplace, these standards are not comprehensive or uniform, and this small number of state laws is not sufficient to adequately protect the vast majority of American workers. Nonetheless, the fact that the states are beginning to recognize the need for regulation of this type indicates the need for national, uniform standards to address a problem which, as Congress recognized in the OSH Act and in subsequent oversight hearings, is of

nationwide scope. The proposed standard will help to avoid the potential for conflicting state-imposed burdens on interstate commerce.

The proposed hazards identification standard has been developed as the second major component of a total information system designed to convey to workers information essential to awareness of existing and potential job related health hazards. The first component of this system is OSHA's standard on Access to Employee Exposure and Medical Records, 29 CFR 1910.20 (45 Federal Register 35212 *et seq.*, May 23, 1980), which provides employees exposed to toxic substances and harmful physical agents with access to their employer-maintained exposure and medical records.

The information provided by the existing access standard and the proposed hazard identification standard is complementary, and without the type of information provided by either standard, the ability of workers to understand and react to significant workplace hazards will be significantly diminished. The access standard generally assures employees access, upon request, to information concerning the identification of toxic substances and harmful physical agents to which they are exposed, as well as access to other exposure and health information, if such information has been recorded by the employer. Access by employees to such records thereby provides an early warning system of possible occupational health hazards and is crucial to the overall purposes of the Act. The access standard does not, however, require the creation of such records. The hazard identification standard, therefore, will significantly add to the informational rights provided to employees in the access standard by affirmatively assuring that chemical manufacturers and users will establish hazard identification systems within their workplaces. Furthermore, unlike the access standard, the hazards identification standard is designed to assure that hazards-related information will flow from the manufacturers and importers to the downstream employees of industrial users, who, because of the trade name problem, are themselves often unaware of the identities or hazards posed by chemicals in their workplaces. Accordingly, to provide anything less than the basic information afforded by these twin standards would deprive workers of the right to protect themselves from danger.

The two rules do, however, in some situations overlap; thus there may be a need to modify the language of the

access standard upon final promulgation of a chemical identification and labeling standard. Comments are invited as to which provisions, if any, in the access standard should be changed in light of the hazard identification standard. OSHA does not anticipate substantial alterations in the content of the Access standard, but does intend to make necessary conforming amendments so that similar terms are used consistently in both rules.

II. Background to the Hazard Identification Standard

A. Introduction

According to data obtained from the National Occupational Hazards Survey conducted by the National Institute for Occupational Safety and Health (NIOSH), approximately 25 million American workers, or one in four, are potentially exposed to one or more of the nearly 8,000 hazards identified by NIOSH (see references 1, 25, 26, and 27). Occupational exposure to the hazardous substances covered by this proposed standard is common. The proposed standard will provide information on potential hazardous exposures to the approximately 20.5 million people employed in the nearly 328,000 manufacturing facilities in SIC categories 20-39, including one million workers in the chemical industry (31). In addition, workers in other SIC categories will obtain partial information on potential hazardous exposures because the proposed standard requires that labels, once attached, remain affixed to containers with hazardous contents.

In its General Industry Standards (29 CFR Part 1910, Subpart Z), OSHA regulates approximately 430 toxic substances, a small percentage of the total number of toxic or hazardous materials present in the workplace. According to the Toxic Substances Control Act Chemical Substances Inventory (TSCAI) compiled by the Environmental Protection Agency (EPA), as of July, 1980, there are approximately 55,103 chemical substances which are manufactured, imported or processed for commercial purposes in the United States (4). The TSCAI figure includes only those substances which are covered by the Toxic Substances Control Act, and does not include many other substances, such as food additives, drugs, cosmetics, and pesticides, which can pose a hazard in the workplace. In addition, approximately 1,000 new chemicals are marketed each year. Thus, only gross estimates can be made of the total number of toxic or hazardous chemicals to which the American worker may be

exposed, as well as the number of workers who are exposed to such substances. The data does indicate that both of these figures are extremely large.

The number of occupational illnesses resulting from occupational exposure to hazardous substances is difficult to quantify. The most comprehensive figures are compiled by the Bureau of Labor Statistics (BLS) in an annual survey of approximately 200,000 industrial facilities entitled, "Occupational Injuries and Illnesses in the United States by Industry." BLS reported approximately 168,000 new cases of occupational illness in 1976, and 162,000 in 1977. These figures do not include the number of workers totally disabled from occupational illness due to chemical exposures who have left the workforce.

An analysis of the survey reveals that 54.7 percent of occupational illnesses in 1976, and 57.9 percent of occupational illnesses in 1977 fell into the categories of illnesses (not counting malignant and benign tumors) most likely to be related to chemical exposures. This comes to a total of more than 180,000 illnesses in those two years, some of which are attributable to exposures which might have been avoided by proper labeling.

The BLS report also indicates that a large number of the total occupational illnesses recorded occur in manufacturing industries (SIC Major Groups 20-39). In 1976, employees in manufacturing industries reported 57.5 percent of all occupational illnesses, but accounted for less than 30 percent of total employment. The 20 industries with the highest rates of occupational illness were all manufacturing industries.

Although these figures are substantial, they probably underestimate the magnitude and severity of occupational illness and injury. The BLS reports that:

The recording and reporting of illness continue to present some measuring problems, since employers (and even doctors) are often unable to recognize some illnesses as being work related. The annual survey includes data on only current and visible illnesses of workers; it does not include data on illnesses which might surface later.

Occupational diseases caused by chemical exposures are often not recognized as such, and thus under-reporting of chemically-caused occupational disease is a major problem. To assess the accuracy and completeness of worker compensation reports and OSHA Form 200 reports, the University of Washington conducted a two-year study for NIOSH which was published in 1975 (52). Medical examination of over 900 employees revealed 346 cases of "probable occupational disease". These were so classified only if the observed

manifestations of the disease were consistent with those known to result from excessive exposure to a specific injurious agent, and the patient was known to have had significant contact with the particular agent during the course of a normal working day. Of these 346 cases, only 8 had been recorded on either the OSHA Form 200 or in worker compensation reports.

B. Survey Estimates of Potential Workplace Hazardous Exposures

The lack of adequate chemical substance identification in the workplace was investigated as part of the National Occupational Hazards Survey undertaken by NIOSH in 1972 (1, 25, 26, 27).

The NIOSH surveyors visited over 5,200 industrial plants that had been selected by the Bureau of Labor Statistics as a representative cross-section of industry type and size. General information was collected about each plant, such as its major product or service, the number of employees, and the availability and kind of medical care. The surveyors then conducted walk-through inspections of each facility to record worker exposures to specific health hazards. The NIOSH teams observed each process in the plants, recorded the number of workers in each job category, and listed the specific chemical and physical agents to which these workers were potentially exposed.

If an employee was exposed to a trade-name product, the surveyor recorded the name of the product, its manufacturer, and the ingredients listed on the product container. If labels on the containers did not list the ingredients, the surveyors tried to ascertain the composition from material safety data sheets or other sources at the plant. All these sources supplied the needed information for only 10% of the trade-name products.

The following is a summary of the NIOSH findings in regards to the adequacy of chemical substance identification in the workplace (25, 26, 27):

Table 1.—NIOSH Findings

1. 85,000 individual trade-name products were identified.
2. These 85,000 products accounted for 70% of all recorded exposures. The remaining 30% of these exposures were either properly identified chemicals or physical agents.
3. The total number of 'hazardous' exposures represented by these trade-name products is not known, since NIOSH was unable to identify the chemical composition of all of these products.
4. In 90% of the trade-name product cases, neither the employer nor the employee knew the identity of the chemicals in the trade-name products.

NIOSH attempted to further identify the trade-name products by contacting the product manufacturers. This effort was complicated by the problem of "nested" trade names—that is, when the manufacturer supplied NIOSH with information on the chemical substances contained in trade-name products, approximately one-third contained secondary trade-name chemicals. If the secondary trade-name composed more than 10 percent of the mixture, NIOSH also pursued identification of it by contacting the manufacturer.

NIOSH contacted over 10,000 manufacturers to obtain additional information on the chemical identification of the trade-name products. At the time they reported their findings to Congress in 1976, NIOSH had obtained product ingredient information on over 40,000 trade-name products. The following is a summary of NIOSH findings in regards to trade-name products (TRN) (25, 20):

Table 2.—Potential Exposure to TRN Products Containing Hazards

Total number of trade name products = 45,404
Total number of employees exposed to TRN products = 278,324
Total number of exposures for employees named above = 1,420,717
Of the total number of employees exposed to TRN products, the number exposed to OSHA-regulated chemicals = 128,028
Total number of exposures for the above employees = 303,667
Percentage of employees exposed to OSHA-regulated chemicals = 45%
Of employees exposed to TRN products which contain OSHA-regulated chemicals, the number of employees exposed to products whose composition is deemed to be a trade secret = 66,727
Total number of exposures for the above employees = 113,665

Table 3.—Potential Exposure to TRN Products Containing Carcinogens

Number of TRN products that contain at least one of the 15 OSHA regulated carcinogens = 427
Total number of employees exposed to TRN products containing carcinogens = 5,638
Total number of carcinogen exposures for employees named above = 7,132
Percentage of employees exposed to carcinogens = 2%
Total number of employees exposed to TRN products containing carcinogens which the manufacturers call trade secret = 2,830
Total number of exposures for employees named above = 3,274

*Number of regulated carcinogens = 16

The NOHS survey promoted the Committee on Government Operations, in its report on chemical dangers in the workplace, to state that they thought the NOHS "disclosed alarming conditions." They further indicated that:

[T]he problem of worker and employer ignorance of hazardous substances used in industry is far greater than previously supposed. The chief cause is the practice of identifying chemical compounds by trade names without the disclosure of ingredients, which thwarts even the most conscientious attempt to alert workers to exposures beyond specified limits.

They concluded:

It is clear that the major objectives of the Act override narrow self-interest on the part of manufacturers. No trade secret can justify exposing great numbers of American workers to cancer-causing agents or other toxic chemicals. Any trade-name product containing a substance known to be hazardous or a carcinogen must be clearly labeled so that precautions may be taken.

The NOHS survey thus provided strong evidence that chemical substance identification was not sufficiently widespread to protect employees adequately, and that an OSHA standard in this area is necessary to provide such protection.

C. Previous Recognition of the Need for Labeling

For nearly sixty years, various government, industry and professional organizations have recognized the need to label hazardous substances, and have sought to identify relevant issues, as well as to develop comprehensive and consistent systems. Several of the more recent documents of significance will be discussed.

1. Occupational Safety and Health Administration (OSHA) Standards: The Occupational Safety and Health Act, 29 U.S.C. 651 *et seq.*, was passed to assure safe and healthful working conditions for working men and women (5). Section 6(b)(7), one of the sections which delegates OSHA the authority to promulgate labeling requirements, states:

Any standard promulgated under this subsection shall prescribe the use of labels or other appropriate forms of warning as are necessary to insure that employees are apprised of all hazards to which they are exposed, relevant symptoms and appropriate emergency treatment, and proper conditions and precautions of safe use or exposure.

Several of OSHA's safety and health standards for General Industry in 29 CFR Part 1910(3) were subsequently promulgated with such labeling requirements for a relatively small number of specific substances. (These standards are listed in Tables 4 and 5 of section (C) below).

2. National Institute for Occupational Safety and Health (NIOSH) Criteria Document: OSHA and NIOSH have long recognized the desirability of a uniform and complete system to identify

hazardous materials found in the workplace. Under section 22(c)(1) of the OSH Act, which authorized NIOSH to develop recommended occupational safety and health standards, a criteria document was published in 1974 which was entitled, "A Recommended Standard . . . An Identification System for Occupationally Hazardous Materials" (7). The recommended standard was designed to inform employees of potentially hazardous materials which are encountered in the workplace by a three-component warning system, including the use of placards, labels, and Material Safety Data Sheets.

A "hazardous material" was defined by NIOSH as "a substance or mixture of substances having intrinsic properties capable of producing adverse effects on the health or safety of the worker". NIOSH recognized that all materials "can cause unwanted changes under some circumstances, but a careful assessment of properties and circumstances will classify common substances such as water and sodium chloride as practically nonhazardous materials from the viewpoint of the need for informing the worker".

NIOSH further refined their definition of hazardous by stating that a material would be considered hazardous if it met any one of the following criteria:

"(1) Toxicity—A toxic substance is one that has demonstrated the potential to: endanger human life by exposure via any route found in the workplace; produce short or long-term disease or bodily injury; affect health adversely; induce cancer or other neoplastic effects in man or experimental animals; induce a transmissible change in the characteristics of an offspring from those of its human or experimental animal parents; or cause the production of physical defects in the developing human or experimental animal embryo.

"In the absence of human or animal effects data described above, a toxic substance is one that produces death in experimental animals exposed to the substances in quantities and by routes which are reasonable . . . The following cut-off points apply to animal exposure data:

A single oral LD50 of up to 5,000 mg/kg.
A single inhalation exposure 1 C 50 of up to 10,000 ppm for gases, or 100,000 mg/cu m by volume for mists or dusts.
A single skin absorption (percutaneous) LD50 of up to 2,000 mg/kg."

"(2) Flammability—A flammable substance is one that will burn in air when exposed to a temperature of 1,500 F (815 C) for a period of five (5) minutes or less."

"(3) Reactivity—A reactive substance is one that will release hazardous amounts of energy when subject to shock, spark, or light, during uncontrolled polymerization, or when contacted by common substances, e.g., water, air, or steel, or is a strong oxidizing or reducing material."

NIOSH further recommended that all materials that are toxic, flammable, or reactive be rated as to their relative hazard. For example, a toxic substance could be rated in any one of five toxicity categories, ranging from "no significant health hazard" (zero rating) to "extreme health hazard" (rating of four). Specific criteria for determining in which category a substance should be included were also recommended by NIOSH. Information to be used by the employer to determine the appropriate hazard rating was to be assembled from "reference sources, expert opinion, and direct experience and familiarity with the material or specific combination of materials". NIOSH also noted that references are "major sources of information on hazardous materials, but many other sources are equally valuable and should not be neglected."

No specific guidance was provided for employers to assist them in making the hazard determinations necessary to comply with the requirements of the NIOSH recommended standard. NIOSH simply stated that following a review of available information, "a composite statement of the potential hazard from the standpoint of health effect, flammability, and reactivity can then be formulated. The proper relative hazard ratings are then assessed by a comparison of the summary data with the tables and relative rating definitions." For health effects assessments, employers were directed to use available human experience data before using animal data, and to rate on the basis of the "worst effect" when both acute and chronic data are available. NIOSH did not provide any examples of how specific substances would be rated according to their recommended classification scheme.

In addition to labels, NIOSH recommended that employers be required to have a Material Safety Data Sheet (MSDS) for each hazardous material or mixture of hazardous materials. A format for the MSDS was also recommended by NIOSH, and included the following categories of information:

1. Product Identification
2. Hazardous Ingredients
3. Physical Data
4. Fire and Explosion Data
5. Health Hazard Information
6. Reactivity Data

7. Spill or Leak Procedures

8. Special Protection Information

9. Special Precautions

3. Report of the OSHA Standards Advisory Committee. In 1974, the OSHA Standards Advisory Committee on Hazardous Materials Labeling was formed in accordance with Section 7(b) of the OSH Act (8). The purpose of this committee, which was comprised of experts representing employers, employees, the Federal government, state governments, and the public, was to develop generic guidelines for the implementation of Section 6(b)(7) of the OSH Act. The recommendations of the Committee involved a "total systems" approach to the problem of labeling. This approach included classification of hazards and the use of warning devices, such as labels and placards, coupled with the use of physical/chemical data and employee training programs. The Committee "identified and confined its discussion to four categories of hazards, namely, flammability hazards, health hazards, reactivity hazards, and materials hazardous by reason of being under pressure in their container". For each of these categories, a number of sub-categories were developed and the Committee recommended the criteria a substance would have to meet to be included in these sub-categories. Wherever possible, the Committee defined these criteria similar to currently used and accepted definitions. For example, the definition of "unstable (reactive) material" was that which OSHA already used in 29 CFR 1910.106(a)(20). The Committee recommended adoption of such a labeling standard to serve both employer and employee by providing a safer and more healthy working environment. The final report of the Committee was submitted to the Assistant Secretary of Labor on June 6, 1975.

In terms of health hazards, the Committee recommended that a labeling standard be developed by OSHA to cover any material which is:

- a carcinogen;
- a corrosive to eyes;
- a corrosive to skin;
- extremely toxic;
- highly toxic;
- an irritant;
- a mutagen;
- a strong sensitizer;
- a teratogen; or
- toxic.

The Committee defined each of these terms, and based their definitions on available test methods wherever possible. However, in some cases they determined that the issues involved

were so complex that the Committee thought resolution of them should be left to the Secretary of Labor. Carcinogens, mutagens, strong sensitizers, and teratogens were thus defined very generally, and OSHA would not have been able to incorporate the Committee's recommendations into a standard without further refining these definitions.

The definitions of "extremely toxic", "highly toxic", and "toxic" were based on estimates of lethal dose. For example, the following are the criteria recommended for determining that a material is "extremely toxic":

"(i) a material that has a median lethal dose (LD50) of 5 milligrams or less per kilogram of body weight when administered orally to albino rats weighing between 200 grams and 300 grams each; or

"(ii) a material that has a median lethal dose (LD50) of 20 milligrams or less per kilogram of body weight when administered by continuous contact for 24 hours or less with the bare skin of albino rabbits weighing between 2 kilograms and 3 kilograms each; or

"(iii) a material that has a median lethal concentration (LC50) in air of 50 parts per million by volume or less of gas or vapor or 0.5 milligrams per liter or less of mist, fume or dust when administered by continuous inhalation for one hour or less to albino rats weighing between 200 grams and 300 grams each."

Given this type of definition for toxicity, it is clear that chronic effects other than carcinogenicity, mutagenicity or teratogenicity would not be specifically covered by the standard recommended by the Advisory Committee. The Committee did recommend that the Secretary retain the right to regulate "special" hazards, not otherwise specifically designated, and assumed this method would be used to cover chronic hazards.

The Advisory Committee did not provide any guidance for employers to determine whether a substance meets the recommended criteria for being toxic. No indication of where employers can find the toxicity data needed to comply with the standard is given. The Committee also did not indicate how employers should assess available data. The question of how to resolve conflicting test results to determine the applicable LC50 was not addressed.

4. American National Standards Institute (ANSI) Standard. Industry also recognized the need for an official standard for the precautionary labeling of hazardous chemicals used in the workplace. In 1944, the Manufacturing Chemists Association, since renamed

Chemical Manufacturers Association (CMA), a trade association composed of members of the chemical industry, established their Labels and Precautionary Information (LAPI) Committee. This committee produced the first published guide to precautionary labeling for hazardous chemicals (Manual L-1) in 1946. In 1970, the LAPI voiced their strong support for precautionary labeling being part of worker safety programs in the following statement:

Precautionary information should, as far as is practicable, reach every person using, handling, or storing hazardous substances. The most practical means of disseminating this information has been found to be by precautionary labels, affixed to containers of hazardous substances, bearing appropriate precautionary statements expressed as simply and briefly as possible. (Manufacturing Chemists Association, *Guide to Precautionary Labeling of Hazardous Chemicals*, Manual L-1, 7th ed. 1970, p. 9).

A subcommittee of the LAPI Committee also assisted in the development of the American National Standards Institute (ANSI) standard entitled "American National Standard for the Precautionary Labeling of Hazardous Industrial Chemicals" (8). This standard, published in 1976, is considered to be the official guideline for voluntary use by industry for the precautionary labeling of hazardous chemicals used in industrial operations.

Some industry representatives have maintained that an OSHA labeling standard is not necessary because industry already voluntarily complies with the ANSI standard. However, findings of the National Occupational Hazards Survey (NOHS) demonstrated that this is not the case in many situations. The ANSI standard is nearly identical to the manual produced by the CMA for its member companies. As stated above, this manual was first available in 1946. However, the NOHS found that CMA member companies did not fare well in terms of identifying dangerous products to purchasers. As reported in 1976 by NIOSH to the House of Representatives' Committee on Government Operations (26), CMA members manufactured almost 9,000 of the trade-name products found in the NOHS, and designated over 3,000 of these as trade secrets. In addition, over 3,000 of the 9,000 trade-name products contained OSHA-regulated chemicals, and 1,440 of these products were among those that CMA members had designated as trade secrets.

The ANSI standard applies to the precautionary labeling of "hazardous chemicals used under industrial occupational conditions". "Hazardous

chemical" is defined as "a chemical or mixture of chemicals that is toxic, highly toxic, irritant, corrosive, a strong oxidizer, a strong sensitizer, combustible, flammable, extremely flammable, dangerously reactive, or pressure-generating, or which otherwise may cause substantial illness during or as a direct result of any customary or reasonable foreseeable handling or use". Each of the specific listed hazards is individually defined by ANSI. However, no definition or guidance is provided to help employers determine what a "substantial illness" is, or which substances may cause such illnesses.

The definitions of "toxic" and "highly toxic" involve lethal dose

determinations. Thus chronic effects are not specifically addressed by the ANSI standard. In fact, the ANSI standard is even less protective in terms of chronic effects than the Advisory Committee's recommended standard would be since even carcinogenicity, mutagenicity, and teratogenicity are not covered by ANSI.

Furthermore, the ANSI standard does not specify the precise mode of identification required, simply stating that it should be "adequate to permit selection of proper action in case of exposure". ANSI also does not specify what percentage of a mixture a hazardous component must comprise to trigger the identification requirements, but indicates that "those compounds which contributes substantially to the hazard(s) shall be identified".

The House of Representatives' Committee on Government Operations concluded on the basis of their evaluation of testimony presented at their hearings that the ANSI standard does not adequately cover chemical substance identification (26). There were two major reasons for their conclusions. First of all, the ANSI standard is a guide for industry, and there is no requirement for industry to comply with such a guide. Second, the Committee recognized that the ANSI standard does not address chronic effects. Their report stated:

A second problem with the ANSI standard is that, like the MCA guide, it is deficient in recognizing potential harm from continuous low-level exposures. It does not include labeling guidelines for chemicals that can cause cancer or genetic defects. Without such labeling, all known hazards are not addressed.

Most recently, the issue of labeling in the workplace was addressed in "An Interim Report to the Congress on Occupational Diseases," submitted by the U.S. Department of Labor in June, 1980 (2). In this report, OSHA indicates the importance of including in its health standards requirements for the use of hazard warning signs or labels. In health

standards which regulate workplace exposures to hazardous substances, such labeling provisions are considered to be necessary to the primary prevention of occupational disease by informing workers of the dangers due to exposure and of methods of prevention. Other primary means of preventing occupational disease, to be used in conjunction with labeling, include employee exposure monitoring, medical surveillance, and training, as well as compliance with permissible exposure limits to regulate employee exposures to hazardous substances.

D. Selected Labeling Regulations Which Are Currently in Effect

1. *Occupational Safety and Health Administration (OSHA)*. OSHA's safety and health standards for General Industry, 29 CFR Part 1910, were either adopted from voluntary consensus standards, in accordance with Section (6)(a) of the OSH Act, or were promulgated by OSHA through the rulemaking process prescribed by section (6)(b) of the Act (3, 5). Several standards from both sources currently contain provisions for labeling hazardous materials which are present in the workplace.

A number of the standards OSHA adopted under section (6)(a) of the Act require employers to placard, label or mark various types of work sites or containers (see Table 1). For example, 29 CFR 1910.103 covers hydrogen. The standard requires the employer to permanently placard hydrogen storage locations with a warning equivalent to: "HYDROGEN—FLAMMABLE GAS—NO SMOKING—NO OPEN FLAMES". In addition, a portable container of hydrogen must be legibly marked with the name "Hydrogen", in accordance with "Marking Portable Compressed Gas Containers to Identify the Material Contained" ANSI Z48.1-1954.

Another OSHA safety standard which addresses labeling of hazardous materials is 29 CFR 1910.252, which covers welding, cutting and brazing. For example, containers of welding materials with significant amounts of cadmium in them must be marked as follows:

WARNING
CONTAINS CADMIUM—POISONOUS
FUMES MAY BE FORMED ON
HEATING

Do not breathe fumes. Use only with adequate ventilation such as fume collectors, exhaust ventilators, or air-supplied respirators. See ANSI Z49.1-1967.

If chest pain, cough, or fever develops after use, call physician immediately.

4.4 Safety Standards Adopted of the Act Which Con- Requirements

	storage labeling required	Container labeling required
soluble.....	X	X
.....	X	X
.....	X	X
amino.....	X	X
.....		
prevent.....		
cutting,	X	X

OSHA health standard under section (6)(a) of the Act, 19000, Air Contaminants, include labeling provisions. Each of the other health standards which were promulgated for substances under section 6 of the Act, do include provisions for signs and labels. The requirements required under each standard are specific to the substance regulated. Each sign or label must contain the precise chemical name of the substance, as well as any hazard warnings or other measures are indicated in the standard. Table 5 is a compilation of the standards, including the section of the Act, the substance covered, the hazard or other information to be included on the label.

- Subpart Z standards Which Contain Labeling Requirements

Substance	Information on label
Breathing dust may cause serious bodily harm.	
Biphenyl.....	Cancer-suspect agent.
Chloro-.....	Cancer-suspect agent.
(and its)	Cancer agent.
Chromethyl.....	Cancer-suspect agent.
	Cancer-suspect agent.
	Cancer-suspect agent.
Dibenzophenyl.....	Cancer-suspect agent.
Dichloromethane.....	Cancer-suspect agent.
	Cancer-suspect agent.
	Cancer-suspect agent.
Dinitrobenzene.....	Cancer-suspect agent.
	Cancer-suspect agent.
Fluoride.....	Cancer-suspect,extremely flammable gas under pressure.
Air-.....	Cancer-suspect, harmful if inhaled or swallowed.
Oven	Cancer hazard.
Heat.....	May cause acute or delayed lung injury.

Table 5.—Subpart Z standards Which Contain Labeling Requirements—Continued

Sec. No. and substance	Information on label
1910.1044 1,2-dibromo-3-chloropropane.	Cancer hazard.
1910.1045 Acrylonitrile	Cancer hazard.

2. Fair Packaging and Labeling Act.

Congress passed the Fair Packaging and Labeling Act (29) in 1966 to require information to be provided to consumers about the commodities they purchase. Congress stated: "Packages and their labels should enable consumers to obtain accurate information as to the quantity of the contents and should facilitate value comparisons." The Act applies to anyone engaged in packaging or labeling consumer commodities. The Food and Drug Administration is responsible for enforcing the Act in regards to food, drugs, devices or cosmetics which they regulate, while other consumer commodities are regulated by the Federal Trade Commission.

Basically, the Act requires consumer commodities distributed in commerce to be labeled with:

(1) The identity of the commodity, and the name and place of business of the manufacturer, packer, or distributor; and

(2) The net quantity of contents, in whatever measure is appropriate for the package and its contents (weight, linear measure, area).

FDA and FTC have specific regulations describing their implementation and enforcement of the Fair Packaging and Labeling Act. Since the Act is directed towards consumers, compliance with its requirements does not provide information for employees in the workplace.

3. Environmental Protection Agency (EPA). In 1976, the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601 *et seq.*) was passed (18). This Act gives EPA broad authority to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment. Under TSCA, unreasonable risk to human health or the environment may be regulated wherever it occurs. TSCA also emphasizes delayed or chronic effects of chemical exposure, particularly cancer, gene mutations and birth defects.

Under Section 6(a)(3) of this Act, EPA may require that a substance, mixture or article be marked or accompanied by warnings and instructions with respect to its use, distribution and disposal. To date, no labeling rules have been promulgated under TSCA.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*) authorizes EPA to regulate pesticides (19). To carry out its statutory mandate to protect against "unreasonable adverse effects", EPA requires that pesticides be tested prior to registration, which licenses distribution and marketing, to determine their health and environmental effects. An array of acute, subchronic and chronic testing is required, together with environmental chemistry and safety data.

Acute effects testing generally includes acute oral, dermal and inhalation toxicity tests, and skin and eye effects potential. The following table summarizes the acute toxicity categorization scheme utilized by EPA (19):

Table 6.—Toxicity Categories

Hazard Indicators	I	II	III	IV
Oral LD50.....	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5,000 mg/kg.	Greater than 5,000 mg/kg.
Inhalation LC50.....	Up to and including 2 mg/liter.	From 2 thru 2 mg/liter.	From 2 thru 20 mg/liter.	Greater than 20 mg/liter.
Dermal LD50.....	Up to and including 200 mg/kg.	From 200 thru 2,000	From 2,000 thru 20,000.	Greater than 20,000.
Eye effects.....	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity; irritation reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; reversible within 7 days.	No irritation.
Skin effects.....	Corrosive.....	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

Required subchronic and chronic toxicity testing varies, but may include assessment of oncogenic, mutagenic, teratogenic, reproductive, and metabolic effects; other adverse effects on the

central nervous system or hematopoietic system; and histological changes in the organs, including but not limited to liver, kidney, and both male and female

reproductive systems. The extent of chronic testing for a particular pesticide depends on a number of factors, such as the intended use, type of application and chemical family.

It should be noted, however, that many registered pesticides have not been adequately tested to determine chronic effects, and therefore such data is not always available. EPA discussed this lack of data in the preamble to their regulations on conditional registration of pesticides (44 FR 27935; May 11, 1979):

There are many pesticides registered that have not yet been addressed by either the generic standards program, or the RPAR program, and thus may not have been evaluated against the unreasonable adverse effects standard of FIFRA section 3(c)(5). The Agency intends to move ahead rapidly with both programs. Nevertheless, it will be some time before a significant number of pesticides are reviewed within these systems, and an even longer time before chronic hazard studies to serve as a basis for reaching regulatory decisions are completed by registrants. During this interim period, many of the risks associated with the use of pesticides will not be identified or fully quantified * * *

EPA has issued proposed testing guidelines for many of the studies that may now be required during the registration process (21).

Based on the testing results, EPA determines whether a pesticide may cause unreasonable adverse effects, and therefore whether it may be registered. In conjunction with registration, EPA may classify a product for restricted use, a determination that additional restrictions are necessary to prevent unreasonable adverse effects. Further, a pesticide product must be labeled according to Agency-established requirements. Labeling is a significant adjunct to the registration process because under FIFRA, the label is the legal standard by which pesticide misuse is judged. Under Section 12 of FIFRA, it is a violation of the Act to "use a registered pesticide in a manner inconsistent with its labeling", and penalties may be levied under Section 14 of FIFRA for this violation.

EPA specifies that the pesticide label must include the following information (40 CFR 162.10):

1. Product name;
2. Company name and address;
3. Net contents;
4. EPA (Product) Registration number;
5. EPA (Producing) Establishment number;
6. a. Ingredients statement, including the name and percentage of each active ingredient (accepted common name, if there is one, followed by the chemical name);

b. A signal word, based on the acute effects of the pesticide (Danger, Warning, or Caution);

c. A child hazard warning, "Keep Out of Reach of Children";

7. A series of precautionary statements addressing human health, environmental effects on fish and wildlife, and physical/chemical hazards the product may pose;

8. A statement of practical treatment in the event of exposure;

9. If restricted use, a statement to that effect; and

10. Directions for use, storage, disposal, and, if applicable, reentry into areas where the pesticide has been used.

Beyond these specified contents, labels are developed by the individual companies seeking registration and thus may vary in terms of additional contents and appearance for the same product from different producers.

EPA has instituted a Rebuttable Presumption Against Registration (RPAR) procedure to assess the risks and benefits of pesticides that are identified as exceeding a threshold level of hazard (40 CFR 162.11). Initially, identification of RPAR candidates has been accomplished through the registration program. A pesticide placed within the RPAR system is fully evaluated relative to all products and uses affected to determine whether the adverse effects identified are unreasonable. Evidence of either acute or chronic "unreasonable" health effects may result in initiation of an RPAR proceeding. If the adverse effects are demonstrated to be unreasonable during the RPAR, cancellation or denial of registration action may result. Thirty substances have been placed in the RPAR system, and five have been completed.

4. *Food and Drug Administration (FDA)*. The Food, Drug, and Cosmetic Act, administered by the FDA, provides for the labeling of substances which are ingested or come into close contact with humans (24). The following products must be labeled:

- Foods
- Cosmetics
- Prescription drugs
- Over-the-counter drugs
- Animal drugs
- Biologics
- Diagnostics
- Radiological products
- Medical devices

The labels required by FDA are applied to the final products prior to consumer distribution, and do not provide any information or protection for employees in the workplace who may be exposed to hazardous

substances during the production process.

Food is defined as articles used for food or drink for man or other animals, components of such articles, and chewing gum. Section 403 of the Act requires that foods be labeled with the following information:

1. Name and address of the manufacturer, packer, or distributor;
2. Net amount of food in the package;
3. Common name of all nonstandardized foods or the complete name of a food listed in the Standard of Identity;
4. Presence of any artificial flavoring, artificial coloring, or chemical preservative, indicated by the chemical name of the substance;
5. Ingredients by weight (except for certain standardized foods);
6. Food for dietary uses must include information on vitamins, minerals, and other dietary properties; and
7. Imitations must be labeled as imitations.

FDA maintains a list of substances which are directly or indirectly added to food and which are "generally recognized as safe (GRAS)" (21 CFR Part 182). To be included on the GRAS list, a substance's safety must be determined by scientists who are experts in food safety. FDA defines the "safety" of food additives as follows:

"Safe" or "safety" means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use * * * (21 CFR 170.3(i))

Although FDA may determine that a substance is "safe" for purposes of their regulations, this does not mean that the same substances are necessarily "safe" for employees exposed in the occupational setting. Therefore, it seems reasonable that a number of the GRAS substances, as well as other food additives, will be evaluated as hazards under this proposed regulation.

Drugs are defined as articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the U.S., or official National Formulary; or articles used to prevent, diagnose, or treat disease; or articles used to affect function or structure in man or animals (21 U.S.C. 321). Medical devices are regulated separately. Section 502 of the Food, Drug, and Cosmetic Act sets forth the following general labeling requirements for drugs:

1. Name and address of the manufacturer, packer, or distributor;
2. Net amount of drug in the package;
3. List of active ingredients, using established names (the established

name is the official name designated; if there is no such designation, the name used in an official compendium; or if a name is not otherwise available, the common name may be used);

4. "May be habit forming" if the drug contains certain substances such as opium;

5. Quantity of certain specified substances such as alcohol;

6. If a prescription drug:

a. "Caution: Federal law prohibits dispensing without prescription."

b. Quantity or proportion of each active ingredient.

c. Names and quantities of all ingredients if for injection.

d. Recommended dosage.

e. Full information on effects and purposes.

f. Established name in type at least half as high as trade name.

7. If an over-the-counter drug: a. Identity statement followed by general pharmacological category or principal intended action.

b. Quantity of contents.

8. Adequate directions for use including frequency, duration, and route of administration, preparation for use, and other dosage information; and

9. Adequate warnings (indications that the drug has narcotic or habit forming properties; warnings against use by persons having certain medical conditions or by children where use may be dangerous to health, precaution concerning safe dosage and manner of use).

FDA has promulgated extensive specific drug labeling provisions under these general requirements of the Act. These provisions are addressed to either the general categories of prescription or over-the-counter drugs, or to individual, specific drugs.

There may be several stages of labeling during the development and packaging of a drug product. The first involves bulk drug shipments from a pharmaceutical manufacturer to another establishment where the drug will be processed, labeled, or repacked in substantial quantity. This establishment then ships the drug product to a retail firm or other dispensing facility (e.g., a pharmacy). Then the drug is dispensed to a customer.

Bulk shipments are generally exempt from the specific drug labeling requirements of the Act but must bear the statement "Caution: For manufacturing, processing, or repacking." Bulk packages of dosage units (such as tablets or capsules) are not covered by this exemption. Certain bulk shipments of drugs must also bear the statement "Caution: Federal law prohibits dispensing without

prescription" (21 CFR 201.122). If the bulk shipment is to be used in the manufacture, processing or repacking of a new drug, the shipper may be required to add to the warning as follows:

"Caution: For manufacturing, processing, or repackaging in the preparation of a new drug or new animal drug limited by Federal law to investigational use" (21 CFR 201.122(b)).

Labeling requirements for products being shipped from the packager to the dispenser of the drug are different for prescription and over-the-counter drugs.

Generally, prescription drug labeling must meet the following requirements (21 CFR 201.56):

(a) The labeling shall contain a summary of the essential scientific information needed for the safe and effective use of the drug.

(b) The labeling shall be informative and accurate and neither promotional in tone nor false or misleading in any particular.

(c) The labeling shall be based whenever possible on data derived from human experience. No implied claims or suggestions of drug use may be made if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness. Conclusions based on animal data but necessary for safe and effective use of the drug in humans shall be identified as such and included with human data in the appropriate section of the labeling.

The information required is to be presented under the following subject headings, and in this order:

Description.

Clinical Pharmacology.

Indications and Usage.

Contraindications.

Warnings.

Precautions.

Adverse Reactions.

Drug Abuse and Dependence.

Overdosage.

Dosage and Administration.

How Supplied.

If necessary, the following headings may also be used:

Animal Pharmacology and/or

Animal Toxicology.

Clinical Studies.

References.

FDA provides specific guidance indicating what information must be provided under each heading (21 CFR 201.57). In addition, for some individual drugs FDA has promulgated specific provisions requiring certain information to appear on the particular drug's label.

If the packager cannot fit all of this information about the drug on the container label, a package insert may be used to supplement the label.

The information FDA requires is intended for the use of the physician or pharmacist. Labels on dispensed drugs are regulated by the individual State Boards of Pharmacy, and thus vary from state to state.

FDA also has regulations specifying labeling requirements for over-the-counter drugs. Basically, the label must include a statement of identity and a declaration of the net quantity of the contents.

FDA has promulgated a number of regulations for specific drug labeling of both prescription and over-the-counter drugs.

For example, lozenges, mouth washes, gargles and other articles sold over-the-counter for relief of minor irritations of the mouth or throat can only be labeled "for the temporary relief of minor sore throats", if the following statement is also included: "Warning—Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult physician promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by physician."

Cosmetics are articles applied to the human body for cleanliness or to alter appearance. Soap is not classified as a cosmetic. Generally, under the Act a cosmetic label requires the name of the manufacturer, packer, or distributor and statement of weight, but does not require the listing of specific ingredients. An exception is coal-tar hair dyes which must be labeled to warn that they may cause skin irritations, and should not be used for eyebrows or lashes because they may cause blindness. However, FDA has promulgated in its regulations under the Act an additional provision which requires that each cosmetic package "bear a declaration of each ingredient in descending order of predominance, except that fragrance or flavor may be listed as fragrance or flavor" (21 CFR 701.3). The names of the ingredients are to be either the FDA adopted name, or in the absence of one, the common or usual name. If there is no adopted or common name, the chemical or technical name is to be used.

5. *Department of Transportation (DOT)*: Section 105(a) of the Hazardous Materials Transportation Act, which was passed in 1975, gave DOT the authority to regulate the labeling of hazardous materials in transportation which may pose an unreasonable risk to health, safety, or property (22). The Secretary of Transportation is given the authority to designate which substances are hazardous. In addition, the Secretary has the authority to regulate substances which meet the definition of hazardous,

but are not specifically designated as such by the Secretary. The shipper is thus required to determine if an individual substance that is not on the list is hazardous; and thus must be labeled. Hazardous substances may include, but are not limited to, explosives, radioactive materials, etiologic agents, flammable liquids or solids, combustible liquids or solids, poisons (dangerous to life, known to be a human health hazard, or presumed to be a hazard on the basis of animal testing results), oxidizing or corrosive materials, and compressed gases.

Over 1500 individual substances or categories of substances have been designated as hazardous (49 CFR Part 172). Some of the categories are general in nature, and thus the categories cover most substances which are hazardous, but are not specifically or individually designated as such. For example, one category is "drugs, not otherwise specified; Poison B". If a drug fits the definition for a Poison B, it would thus have to be labeled, even though it is not individually listed by DOT by substance name. A table which is part of the DOT regulations indicates the specific labeling requirements for each of these designations.

The hazardous substances which are categorized on the basis of their health effects are designated as either Poison A or Poison B. The substances categorized as "Poison A" are considered to be "extremely dangerous", and those categorized as "Poison B" are considered to be "less dangerous". Approximately 20 individual substances are listed as Poison A, as well as 6 general categories. Nearly 130 substances are considered to be Poison B, and there are about 20 general categories listed as such.

Under DOT regulations, 49 CFR Part 172, all dangerous goods or their packages must have the designated labels. The label must include the name, DOT identification number, and a statement of the hazard. In addition, the regulations require the placarding of each motor vehicle, rail car, or freight container containing any quantity of a hazardous material.

DOT regulations cover interstate shipment by truck, rail, water, or air but vary depending on the mode of transportation. The responsibility for labeling is placed on manufacturers, shippers, and the reconditioners and testers of containers in which the hazardous materials are transported. Both the carrier and the manufacturer are forbidden to transport a package which is improperly labeled.

6. *The Consumer Product Safety Commission (CPSC).* The CPSC regulates the labeling of toxic substances in household products used by consumers as part of its broad mandate to protect the public against unreasonable risk of injury (23). The CPSC administers the Federal Hazardous Substances Act (FHSA) which requires the labeling of hazardous substances. "Hazardous substance" is defined in the FHSA regulations as "any substance or mixture of substances which is toxic, corrosive, an irritant, a strong sensitizer, flammable or combustible, or generates pressure through decomposition, heat or other means, if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children." A "toxic" substance is one which "has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface." A "highly toxic" substance is defined by lethal dose testing results. (These definitions may be found in 16 CFR 1500.3).

The person or firm who releases a product into interstate commerce (usually the manufacturer) has the primary responsibility for determining if the FHSA applies to their product and thus warrants labeling (section (4) of the FHSA). However, if CPSC finds that there may be uncertainty as to the application of the Act in certain instances, or if the hazard is such that the general labeling requirements will not protect consumers, individual specific regulations may be required for hazardous substances. This authority has only been used in a few cases, such as charcoal briquettes (16 CFR 1500.12 and 1500.14) and methyl alcohol (16 CFR 1500.14). CPSC may also ban hazardous substances if the degree of hazard warrants discontinuing consumer use. For example, carbon tetrachloride is a banned hazardous substance (16 CFR 1500.17).

The FHSA requires the following information on a label or tag attached to a hazardous substance:

1. Name and place of business of the manufacturer, packer, or distributor;
2. Common or chemical name of the hazardous substance or of each component which contributes substantially to its hazard;
3. The signal word "danger" on substances which are extremely

flammable, corrosive, or highly toxic;

4. The signal word "warning" or "caution" on all other hazardous substances;

5. Affirmative statement of the principal hazard or hazards;

6. Precautionary measures describing the action to be followed or avoided;

7. Instruction, when necessary or appropriate, for first-aid treatment;

8. The word "poison" for any hazardous substance defined as highly toxic;

9. Instructions for handling and storage of packages if special care is required;

10. Statement "Keep out of the reach of children" or if intended for use by children, adequate directions for the protection of children.

As stated above, if this information is not adequate to protect consumer health and safety, additional requirements may be applicable. For example, special labeling is required at certain concentrations for benzene, toluene, xylene, and petroleum distillates (16 CFR 1500.14).

7. *State Regulations.* Twenty-four states have regulations which address labeling. However, only nine states have regulations which apply to labeling in the workplace environment (9, 10, 11, 12, 13, 14, 15, 16, and 17).

Table 7 lists all of the provisions contained in the state regulations. Also listed, by individual state, are the specific provisions applicable to each. This table was prepared by OSHA to give a general overview of existing state laws based on a review of the written regulations supplied by these states. It should not be considered to be a legal interpretation of these state requirements. Most of the states do not have any provisions pertaining to the protection of trade secret information, nor do they provide employers with any specific guidance for determining which substances in their workplaces are covered by the regulations.

Table 7.—Summary of State Labeling Provisions

Provisions which may be included in state regulations:

1. Substance Identification:
 - (a) Requires substance identification by chemical name or common name(s).
 - (b) Requires substance identification by chemical name and common name(s).
2. Identification Criteria:
 - (a) Includes a list of regulated substances.
 - (b) The employer determines which substances are regulated on the basis of definitions.

Summary of State Labeling Requirements—Continued

... information the employer can use are ...
... of labels and definitions is used.
... of the Safety Data Sheets.
... to be provided on labels or ...
... information.
... information.
... use access to records main-
... by employer.
... station.
... (a)
... (b)
... (c)
... (d)
... (e)
... (f)
... (g)
... (h)
... (i)
... (j)
... (k)
... (l)
... (m)
... (n)
... (o)
... (p)
... (q)
... (r)
... (s)
... (t)
... (u)
... (v)
... (w)
... (x)
... (y)
... (z)

European Community

Dangerous substances are ... between the U.S. and ... labeling ... these nations may have ... labeling ... standards established by ... organization composed of ... is the most widely ... standards in foreign

... were initiated in ... of the European ... that time, the ... four Directives ... classification, packaging ... "dangerous" chemical ... The term "dangerous" is ... definitions of ... Directives require ... of the EEC to ... laws, regulations, ... provisions regarding ... products within a ... of time.

... focuses on a distinct ... materials or ...

... Concerns ... packaging, and ... substances ... EEC, August 16, 1967; ... 79/831/EEC,

... Concerns ... (i.e. mixtures) ... are intended ... 73/173/

... Covers paints, ... adhesives, and ... Directive 77/728/EEC,

... Directive: Covers ... Directive 76/631/

... Directive specifies ... of dangerous

products and the criteria by which they are defined. The EEC categories encompass products that may present health, physical, and environmental hazards during use, handling, or disposal. Eight categories identify products that pose health hazards or degrees of hazards: very toxic, toxic, harmful, corrosive, irritant, carcinogenic, teratogenic, and mutagenic. There are five categories of materials that pose physical hazards: explosives, oxidizing, extremely flammable, highly flammable, and flammable. A final category includes products whose use threatens the environment: dangerous for the environment. A dangerous product is one which can be classified in one or more of these categories.

Containers of dangerous substances that are distributed within the EEC must be labeled with the following information: (1) The name of the substance, (2) the name and address of the manufacturer, importer, or distributor of the substance, (3) hazard symbol(s), if applicable, and key hazard terms, (4) appropriate Risk Statements, and (5) appropriate standard Safety Advice Statements. Terms such as "non-toxic" or "non-harmful" must not appear on any package containing a dangerous substance.

The EEC labeling standard use symbols as the primary hazard warning method. Associated with nine categories are six pictograms: explosives—an exploding bomb; oxidizing—a flame over a circle; extremely flammable and highly flammable—a flame; very toxic and toxic—a skull and crossbones; harmful and irritant—the St. Andrew's cross (a bold-face "X"); corrosive—a symbol showing the destructive effects of an acid dripping from test tubes onto a hand and a bar. Containers of a product which satisfy the criteria for any of these categories must bear the corresponding pictogram(s) and key hazard term(s) on their labels. The pictograms must be printed in black and appear on a rectangular orange-yellow background. Together the pictogram and the hazard term constitute the EEC hazard warning symbol.

For products that satisfy the criteria for more than one of the danger categories, the EEC prescribes procedures for determining which pictograms take precedence over others on the label. These requirements determine which of the hazards are to be highlighted on the label by symbols (and, therefore, which are left to be dealt with by means of appropriate risk statements). A label may contain no more than two symbols.

The EEC has established specific labeling requirements for nearly 1,000

dangerous substances, which appear in an appendix to the Substance Directive. These requirements specify precisely what information must appear on the product's label, including the nomenclature for identifying each substance, hazard symbols, and standard risk and safety statements. However, substances which meet the criteria for being dangerous but do not appear in this appendix, must still be labeled.

The Substance Directive will go into effect in September 1981. The Paints Directives became effective on November 7, 1979; the Solvents Directive on June 4, 1976; and the Pesticides Directive on January 1, 1981.

E. History of OSHA's Proposed Labeling Standard

OSHA's involvement in the identification and labeling of hazardous chemicals in the workplace began several years ago. In 1974, the Standards Advisory Committee on Hazardous Materials labeling was established under Section 7(b) of the OSH Act to develop guidelines for the implementation of Section 6(b)(7) of the Act with respect to hazardous materials. On June 6, 1975, the Committee submitted its final report which identified issues and recommended guidelines for categorizing and ranking chemical hazards. Labels, data sheets, and training programs were also prescribed.

In 1976, Congressman Andrew Maguire (New Jersey) and the Health Research Group petitioned OSHA to issue a standard to require the labeling of all workplace chemicals. The House of Representatives' Committee on Government Operations in 1976 and 1977 recommended that OSHA should enforce the health provisions of the OSH Act by requiring manufacturers to disclose any toxic ingredients in their products, and by requiring employers to disclose this information to workers (House Report No. 94-1683 and House Report No. 95-716).

On January 28, 1977, OSHA published an advance notice of proposed rulemaking on chemical labeling in the Federal Register (42 FR 5372). The notice requested comments from the public regarding the need for a standard which would require employers to label hazardous materials. Information was also requested regarding the provisions to be included in such a standard to assure that employees are apprised of the hazards to which they are exposed.

A total of eight-one comments were received from a variety of federal, state, and local government agencies, trade associations, businesses, and labor

organizations. In general, there was support for the concept of a chemical identification and labeling standard. A number of commenters said that such a standard should be comprehensive in scope, but not too complex in design. Many expressed the opinion that OSHA's standard should be compatible with the standards of other regulatory agencies with labeling authority, such as the Department of Transportation (DOT), and with existing voluntary labeling standards, such as that of the American National Standards Institute (ANSI). A few commenters expressed concerns about protection of trade secret information and about labeling chemical intermediates.

Various suggestions were put forth for determining which materials should be covered by the standard. Some commenters thought that chemicals which met specified definitions or other classifications should be regulated. Others preferred that a list of substances to be regulated be provided, for example, those substances in 29 CFR 1910.1000 (OSHA's list of air contaminants), in the NIOSH Registry of Toxic Effects of Chemical Substances (RTECS), or in the DOT hazardous materials list.

Virtually all commenters recognized the need for labels in the workplace, and for inclusion of warnings and descriptive information. However, opinions varied as to what form these labels and information should take, or if an existing system should be adopted. Similarly, there was general recognition of the need to inform employees of the hazards to which they are exposed by means of data sheets and training programs, although suggestions as to content and format varied.

In developing this proposal, OSHA has considered all of the regulations, documents, and comments described above. Consideration has also been given to all other available information, such as that presented at conferences and at meetings of professional societies, and meetings with interested members of the public and other Federal agencies.

In addition, as a member of the Interagency Regulatory Liaison Group (IRLG), OSHA is working to assure that the provisions of this standard will not conflict with other related federal policies and regulations. The IRLG, which was established to coordinate federal regulatory activities, consists of representatives from OSHA, the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the Consumer Product Safety Commission (CPSC), and the Food Safety and Quality Service of the

Department of Agriculture. The "IRLG Labeling Regulations Task Force" and the "IRLG Labeling Education Task Force Group" are currently involved in planning research projects to determine the factors that contribute to effective labeling. OSHA recognizes the need for such research. However, the evidence found and presented in this document indicates that immediate action should be taken to protect employees. The IRLG deliberations and research findings will be entered into OSHA's rulemaking record as they become available, and will be given full consideration in the development of OSHA's final standard.

III. Summary of the Proposed Standard

The proposed hazards identification standard will establish a system designed to communicate to workers, employers and governmental agencies concerned with worker health, the essential facts necessary to assess the hazards of workplace chemicals. Chemicals are classified under the proposal as either "substances" or "mixtures." Information about the identities and hazardous properties of hazardous chemicals will be communicated primarily by means of labels and placards, and material safety data sheets. Container labels and placards will give workers immediate access to the identities of the hazardous chemicals and mixtures with which they work directly. Safety data sheets, when available, will provide workers and their representatives with detailed information about the properties and handling of hazardous chemicals and mixtures, supplementing the information on hazard warning labels. Hazard evaluation files will enable employees and their representatives to do their own hazard determinations and to check those done by the employer.

The key responsibility under this system for the evaluation of hazards lies with the manufacturer or importer of a substance or mixture of substances. This is because the manufacturer or importer is in the best position to know the chemical identity and properties of a substance or mixture.

The proposed hazard identification standard requires each manufacturer to evaluate each substance and mixture the manufacturer makes to determine if it is hazardous according to criteria the standard specifies. Importers of substances and mixtures destined for the workplaces of industrial users must evaluate them under the same criteria.

The evaluative procedures of the proposed standard do not require manufacturers and importers to test substances and mixtures for hazards. They do require a manufacturer or

importer to determine whether any of the substances or mixtures which they manufacture or import poses a physical hazard (Category A hazard) or an acute or chronic health hazard (Category B hazard). To make this determination, the manufacturer is required to assemble scientific materials from specified sources, including both private and publicly available materials by means of the evaluation schemes set out in Appendices A and B.

Manufacturers and importers must maintain files on all chemicals and mixtures they manufacture or import. Each file must contain the references, studies, reports, or other documents upon which a conclusion of hazard, or lack of hazard, is based.

With certain shipments of chemical substances or mixtures from their premises, manufacturers and importers must forward the following information:

The precise identity of hazardous substances, and the identity of hazardous constituent substances which are part of a mixture;

An appropriate hazard warning and precautionary statement for the hazardous material shipped;

Where a substance or mixture has been determined not to meet the standard's criteria for a hazard, a statement to that effect.

This information must accompany shipments to any employer whose activities are classified under Division D (Manufacturing), Major Groups 20-39 of the Standard Industrial Classification Manual. These are employers who manufacture, process, formulate or use chemicals, and who are referred to in the proposed standard as "industrial users." This information must also accompany shipments to suppliers who will subsequently distribute a hazardous substance or mixture to an industrial user.

The proposed standard does not require manufacturers and importers to develop safety data sheets on the hazards of chemicals and mixtures. With the first shipment of a hazardous chemical or mixture to a workplace of an industrial user or a supplier of an industrial user, however, a manufacturer or importer must forward one copy of the most current safety data sheet which the manufacturer or importer does have concerning the dangers posed by the material shipped. A supplier must forward with every shipment to another supplier or to an industrial user the hazards-related information received from a manufacturer or importer. A supplier has no other duties under the proposed standard.

Industrial users are employers who manufacture, process, formulate or

otherwise use chemicals and mixtures. Thus, the manufacturer of a particular substance or mixture is also an industrial user. Protection of the employees of industrial users is the primary purpose of the hazards identification standard. To insure that employees of industrial users know the hazards of the substances and mixtures with which they work, the hazard identification standard would require such industrial users to:

Label containers of every hazardous substance in the workplace with the CAS number and common name of its contents, and with appropriate hazard warnings.

Label containers of mixtures with the CAS number and common name of its hazardous constituent substances, and with appropriate hazard warnings.

Provide employees with any available safety data sheets concerning the dangers posed by hazardous chemicals and mixtures in the workplace.

Update the information provided to employees as new information about the hazards of a substance or mixture become available.

Triggering the responsibility to label and to provide available safety data sheets is the determination that a substance or mixture is hazardous. In determining if a workplace substance or mixture is hazardous, only the manufacturer or importer of that substance or mixture need undertake a review and evaluation of internal records and of the scientific literature. Other industrial users of the substance or mixture may simply rely upon the determination made by the manufacturer or importer. These determinations will be evidenced by the hazard-related information received by industrial users with shipments of substances or mixtures from manufacturers, importers, or suppliers.

The proposed hazard identification standard would also provide employees, former employees, and their designated representatives, with access to safety data sheets relevant to the areas in which the requesting employee works or worked. A designated representative may be anyone the employee chooses, including, but not limited to, a union representative, a physician, or a family member. Union representatives and employees in the workplace would have access to all safety data sheets in the workplace.

Under the proposed standard, employees, former employees, unions representing employees in the workplace and other designated representatives, OSHA, and NIOSH, may inspect any file containing the references and documents upon which

hazard determinations for workplace chemicals and mixtures are based.

Safety data sheets and files containing hazard determination materials must be preserved for specified periods of time. The proposed standard makes provision for permanent transfer of these records in case an employer subject to its recordkeeping requirements goes out of business.

IV. Major Issues for the Rulemaking.

There are a number of major issues inherent in the provisions of the proposal concerning which OSHA specifically invites comment. A brief discussion of some of the most important of these issues follows. There are undoubtedly additional issues raised by this notice of proposed rulemaking which should and will be addressed, and OSHA may amend the proposed standard on the basis of comments received or alternatives discussed concerning such issues.

A. Issues of Scope and Type of Standard

1. *The generic approach to a hazard identification standard.* The proposed hazard identification standard embraces a generic approach to rulemaking. The standard sets out a list of defined hazards; mandates procedures which manufacturers and importers must follow to determine the existence of those hazards, and requires that substances and mixtures meeting any hazard definition be labeled and otherwise identified in various ways. Some industry representatives have strongly objected to the generic approach and have suggested that substances and mixtures in the workplace should be subjected to regulation by the standard on a case-by-case basis.

As discussed elsewhere in this preamble, OSHA believes that it is authorized by applicable law to undertake generic rulemaking. Moreover, OSHA believes strongly that the generic approach to rulemaking is particularly applicable to hazard identification. It is generally accepted among health scientists that literally thousands of chemicals in the workplace are capable of harming human health. Consequently, it would take many years to accomplish comprehensive and effective identification of hazardous chemicals in the workplace if there were separate rulemakings concerning each potentially hazardous workplace chemical. Indeed, in its entire ten (10) year history, through substance-specific rulemakings OSHA has been able to promulgate currently effective standards regulating only 20 chemicals.

The current proposed generic standard places the responsibility for the hazard determination process upon the manufacturer or importer (paragraph (i) of the standard). Without changing any of the other requirements of the standard or abandoning the generic approach, an alternative approach is conceivable in which the Agency itself could undertake to carry out the hazard determination process in the final rule. Thus, the final rule would retain the current scope of hazard coverage, the hazard determination process, the data evaluation scheme and the regulatory requirements concerning hazardous substances or mixtures.

The Agency could perform the hazard determination process in the following manner:

1. Appointed panels of experts would review classes of chemicals using the scientific materials mandated by Appendix A and the data evaluation scheme set out in Appendix B;

2. OSHA would review the expert determination of hazard and require conformity with the provisions of the standard for those substances or mixtures where it approves the expert panel's decision.

3. If an interested party disagreed with the Agency's hazard determination decision, then the Agency could apply a summary procedure to determine whether a hearing were required. Issues in the summary judgment procedure would be confined to the question of whether the quantity and quality of data underlying the positive hazard determination satisfied the rule's requirements.

The Federal Food and Drug Administration (FDA) has extensive experience in the use of the elements just described. Expert panels were utilized to evaluate 16573 claims of effectiveness for 4,000 drug formulations following passage of the 1962 Drug Amendment (see Note: *Drug Efficacy and the 1962 Drug Amendments*, 60 Geo. L. J. 185-224 (1971)). The FDA's summary judgment procedure has been upheld (*Weinberger v. Hynson, Westcott and Dunning, Inc.*, 412 U.S. 609 (1973)). The summary judgment procedure involved regulations which defined, " * * * the essentials of adequate and well-controlled clinical investigations * * * (as a) * * * basis for the determination whether there is substantial evidence to support the claims of effectiveness * * * (21 CFR 314.111(a)(5)(ii) (1979)).

The Agency invites comments on the advisability of this alternative approach. The Agency did not choose this alternative because it believes that the hazard determination process which it has mandated in the proposal will result

in labeling of hazardous materials sooner.

OSHA solicits comments directed at the appropriateness of generic rulemaking in the context of the need for hazard identification in the workplace under either of the two alternative approaches described. Should OSHA conclude that generic rulemaking is inappropriate, OSHA may still adopt a two-tiered approach similar to its Cancer Policy (45 FR 5002 *et seq.*) Under such an approach, the hazard definitions and evaluation procedures proposed in the standard, with any appropriate modifications which arise from comments and testimony, would be adopted generically. Using these, OSHA would then formulate lists of hazardous chemicals which, either individually or in groups, may then be subjected to rulemakings to determine if they should trigger the informational requirements of the proposed standard.

2. Employers covered by the standard. The proposed standard is designed primarily to provide hazards-related information to employees of employers engaged in manufacturing. To this end, the standard regulates the activities of both manufacturers who produce chemicals (called "manufacturers" in the standard) and manufacturers who use chemicals (called "industrial users" in the standard), as well as importers and suppliers of hazardous chemicals. Under the standard, Division D (Manufacturing), Major groups 20-39, in the most recent revision of the Standard Industrial Classification Manual; Executive Office of the President—Office of Management and Budget, defines the class of manufacturers and industrial users covered by the standard. Employers excluded include those in agriculture and construction among others.

It should be noted, however, that the proposed standard intends that where an employer otherwise exempted from coverage works on the premises of a workplace covered by the standard, chemicals utilized by the exempted employer will be subject to the provisions of the standard.

Although evidence is presently lacking, the need for the protections of the hazards identification standard may well be as great in some industries excluded from coverage as they are in those covered. Accordingly, OSHA invites comment on the appropriate scope of coverage. Employers currently excluded from the scope of the proposal may be included in the scope of the final standard if evidence in the record ultimately warrants such inclusion. They and others interested in this issue are therefore given notice that they should

be prepared to participate in the rulemaking and provide justification, if they so desire, of why particular classes of employers should or should not be excluded.

3. Duty to disclose specific chemical identity and impact on trade secrets. A keystone of the proposed hazard identification standard is the duty to provide workers with specific chemical identity of hazardous chemicals. As discussed elsewhere in this preamble, OSHA considers the disclosure of specific chemical identity in addition to basic hazard warning information as crucial to the goal of worker self-protection.

Certain industry representatives have stated that provision of the specific chemical identity of hazardous chemicals is inappropriate. They claim that workers and their representatives generally are neither properly trained or equipped to utilize the chemical identity of hazardous chemicals to decipher additional facts about their effects; nor to develop new modes of treatment for, or prevention of, such effects.

OSHA invites detailed comments on these contentions. OSHA also invites detailed comments from workers and their representatives concerning the need for and uses of the specific chemical identification which the proposed standard would make available to them.

OSHA is particularly interested in this issue because of the likely impact of this standard on employer trade secret interests. The trade secrets issue is presented by the proposal because, in some instances, disclosure of a hazardous substance's chemical identity may involve revelation of a trade secret.

In developing this proposal, therefore, OSHA has considered the effect of this standard on trade secrets. An extended legal analysis of OSHA's authority to issue standards requiring disclosures affecting trade secrets may be found in the preamble to the access to exposure and medical records standard (45 FR 35248-251). In general, OSHA believes that in rulemaking it must balance the safety and health interests in disclosure of hazards-related information with the employer's interest in trade secrets, but that it may require disclosure by rule, notwithstanding a trade secret interest, where non-disclosure could pose a significant risk to employees. In OSHA's view, this means that chemical identities of hazardous chemicals and their hazardous properties must be disclosed to employees, but that the secret chemical identities of non-hazardous chemicals, as well as secret process and formula information concerning hazardous chemicals, need not be

disclosed. OSHA recognizes that the impact on trade secrets of this proposed rule is in some respects greater than the records access rule because of the element of "downstream" disclosure. On the other hand, the more focused scope of the chemicals covered by this standard and the percentage exclusion for chemical constituents of mixtures below 1.0% for non-carcinogens and 0.1% for carcinogens should eliminate some of the anticipated trade secret problems.

Industry representatives have suggested, however, that even where a substance is admittedly hazardous, disclosure of its identity should not automatically be required where a trade secret is involved. These representatives propose that industry be allowed in every case involving a claimed trade secret to challenge the need for disclosure. Presumably, the issue would be whether the potential for harm to workers risked by non-disclosure outweighs the damage to a firm by forced disclosure of its trade secrets in the individual case.

Once a firm has through its own evaluation found a chemical hazardous, OSHA believes that case by case adjudication is unjustified and unworkable. OSHA believes that each of the hazards it has identified in the proposed standard is significant. Consequently, if the potential for a hazard exposure in the workplace exists, disclosure of the identity of chemicals posing that hazard is clearly essential to providing the capability for workers to protect themselves from workplace hazards. Moreover, allowing individual challenges to the need for the disclosure of the chemical identity of hazardous chemicals might well create an administrative nightmare as thousands of challenges to disclosure were lodged. It could take years before a final decision were reached in any case. In the interim, with enough challenges, the standard's requirements for disclosure would be meaningless.

OSHA recognizes that the legal and policy issues surrounding the disclosure of trade secrets are troublesome and complex. OSHA solicits comments on all aspects of trade secrets disclosure and particularly on the following points:

—How important are trade secrets to the competitive structure of the industries covered under the proposal or which may be covered by any final standard?

—To what extent will the proposed standard require trade secrets disclosure?

—Are there ways to provide trade secrets protections greater than those afforded under the proposal, and still

chemical identification is
in a fashion to all those
know?

elements occupy a
the proposed
the extent of
substance or mixture is
the hazard determination
turn, is constructed
elements. The elements are
considered under
scope of hazards
determination process
procedure.

covered by the standard
Universal vs. hazard
proposed standard would
of chemical
hazard warnings for
meet the criteria for
defined by the standard
§ 191.101-1 and Appendices
definitions fall into
categories, Category A and
which generally correspond
health hazards,
and which together are
embrace all significant
hazards.

workplace hazards, the
standard falls short of a
universal chemical
By contrast, some unions
advocates have urged
chemical identification
in the workplace
they pose proven
health. They claim
identification is necessary to
ability of workers, and
them, to identify the
chemicals in the workplace
to worker health actually
worker capability to
studies, these
that the identification
properties of workplace
especially those with long
will be unnecessarily
resultant increase in
of workers.

cluded, however, there
major drawback to
identification of
workplace: disclosure
may, at times,
fact. OSHA believes
disclosure of a trade
justified where the
poses a known
health. With universal
identification, the identity of
may turn out to be
revealed. This, in
potential for unwarranted
industry trade secrets. To
important disadvantage,

workers, and those assisting them,
would have to show a comprehensive
capability of using chemical identity to
determine hidden hazardous effects of
workplace chemicals with no present
known potential to injure human health.

OSHA invites comments concerning
the utility of a requirement for universal
chemical identification in the workplace
and any effects such a requirement
might have upon trade secrets.

b. *General or workplace-specific
hazard determinations.* Under the
proposed standard, the determination of
a hazard is not made dependent on the
particular conditions under which the
chemical will be used in a particular
workplace. Instead, the proposal
provides for a single hazards
determination procedure.

On scientific grounds, OSHA believes
that its proposed approach is preferable.
Traditional public health preventive
practice has considered a substance or
mixture potentially hazardous for any
occupational exposure once its toxicity,
based upon definitions like the ones
presented in this proposal, has been
documented with sound toxicologic,
clinical or epidemiologic studies. This
current Agency position is consistent
with the 1974 NIOSH criteria document
(7).

Moreover, the Agency believes that
adoption of the workplace-specific
alternative would lead to an
unreasonable demand on OSHA
consultation and enforcement resources.
Since manufacturers and importers have
no reliable methods of knowing the
conditions surrounding the end-use of
their chemicals by industrial users,
OSHA believes that the hazard
determination process would need to be
performed in that case by the industrial
users themselves. Industrial users, as a
class, in comparison to manufacturers
and importers, have substantially less
experience in making such basic hazard
determinations for chemicals. As a
consequence, industrial user hazard
determinations would probably take
longer, cost more and require greater
OSHA involvement.

As a result of the single hazard
determination approach of this proposal,
some industry representatives have
stated that the hazard definitions do not
adequately take into account, and may
in fact overstate, the true risk of
potential hazards in the workplace.
Thus, they feel it is unnecessary, or even
harmful, to apprise workers of the
hazards of chemicals tested in one
physical form (solid, liquid, or gas) and
presented in the workplace in another
physical form. OSHA believes that, in
the case of Category B health hazards,
the physical form of a substance is

largely irrelevant to the risk imposed by
the exposure.

Moreover, these industry
representatives would not apprise
workers of the hazards of chemicals
where the existence of a hazard was
established at dosages, or by routes of
administration, not frequently
encountered in particular workplaces.
OSHA invites further comment on this
issue.

c. *Impurities, Intermediates, By-
Products.* The proposed standard would
require that impurities, intermediates,
and by-products be evaluated and
regulated, if known to be present
(paragraphs [d](2)(iv), [e]). OSHA does
not intend that a manufacturer or
importer perform chemical analysis to
detect these materials in order to
comply with this standard.

The Agency expects that its
jurisdiction over these classes of
materials, as potential workplace
hazards, will extend to the point at
which the Environmental Protection
Agency assumes jurisdiction under the
Solid Waste Disposal Act as amended
by the Resource Conservation and
Recovery Act (42 U.S.C. 6907(a)(3),
6944).

OSHA invites comment on the
appropriateness of including these
categories of chemicals in the proposed
standard.

2. *Hazards covered by the standard
(definitional issues).* a. *General.* The
proposed standard covers physical
hazards, acute health hazards and
chronic health hazards. The covered
hazards are categorized into these three
categories as follows:

Table 8

Category		
(A)	(B)	(C)
Physical hazards	Acute/subacute health hazards	Chronic health hazards
Corrosives	Highly toxic material	Sensitizers
Extremely flammable liquids	Toxic materials	Carcinogens
Flammable materials	Irritants	Reproductive toxins
Aerosols, gases	Materials that have condensed or condensed on surfaces	Materials that cause other adverse health effects
Liquids, solids	Materials that cause other acute adverse health effects	
Combustible liquids		
Pyrophoric materials		
Strong oxidizers		
Reactive materials:		
Explosives		
Organic peroxides		
Pressure-generating materials		

Table 8—Continued

Category		
(A)	(B)	(B)
Physical hazards	Acute/subacute health hazards	Chronic health hazards
Water-reactive materials.		
Compressed gases.		

b. Physical Hazards. The Category A (physical) hazards are defined in terms of objective physical properties to facilitate compliance. The definitions for physical hazards are stated in terms of numerical criteria (flammability, combustibility, compressed gas), chemical structure (organic peroxides) or reactive properties (corrosives, pyrophoric materials, strong oxidizers, explosives, pressure-generating materials, water-reactive materials). Based upon discussions with industry and the Agency's own expertise, OSHA believes that data and studies necessary to determine whether a substance meets the objective criteria of the physical hazards' definitions are available either in company files or in the scientific literature. To comply, a manufacturer or importer would evaluate such data or studies for the presence of physical hazards using sound scientific judgment. An extensive literature search is not required (see Appendix A) nor need the formal evaluation scheme be followed (see Appendix B).

In the case of mixtures, the Agency understands that compliance based upon material in the scientific literature will not often be possible because of the scientists' tendency to evaluate the effects of pure substances. However, the Agency believes, based on discussions with industry, that many manufacturers of mixtures obtain the requisite physical hazards data on a proprietary basis as a customary incident of offering the mixture for sale. The Agency has, therefore, provided for the use of such data when available (paragraph (a), Appendix A). In general, however, OSHA does not rely on such mixture data and the standard provides that where data for the mixture as a whole is unavailable, the hazard determination for a mixture reflect the hazards of the constituent substances (paragraph (i) of the regulation and Appendix A).

c. Health Hazards. In addition to physical hazards, OSHA has provided for broad coverage of health hazards. OSHA recognizes that Category B hazard determinations are inherently more complex than Category A hazard determinations. Category B (health) hazard determinations will require greater expenditures of professional time and will call for the exercise of

more sophisticated professional judgments (see Appendix B) than do the more mechanical Category A hazard determinations. Nevertheless, OSHA does not believe that complexity of the task or occasional ambiguities of the data are sufficient reason to omit coverage of various health hazards. Each of the covered health hazards is justified on the grounds that the category represents well-documented medical and/or toxicologic adverse health effects. The Agency believes that it is prudent public health policy to reflect in the proposed standard that range of adverse health effects already documented by occupational physicians, toxicologists and other health professionals.

In view of the complexity inherent in Category B hazard determinations, the proposed standard provides assistance in the form of explicit directions to the manufacturers or importers. The standard describes the hazard determination process (Appendix A), details the materials (including the output of a required literature search) that must be used for the determination (Appendix A) and provides an evaluative scheme for such materials (Appendix B). The Agency believes that the explicit directions for compliance just described reflect the best current scientific practice and will reduce the ambiguities inherent in a less detailed standard, will facilitate compliance and result in many fewer enforcement actions. Extensive discussions with industry have produced no alternative evaluative schemes. Moreover, specification of the Category B hazard determinations process is required to obtain uniformity of labeling.

Nevertheless, representatives of the chemical industry have informally advised OSHA that they believe OSHA's proposed hazard definitions are deficient in at least the following general respects:

—Some hazard definitions could include insignificant health effects that almost any workplace substance or mixture will cause. If this is true, implementation of the hazard identification standard would lead to overlabeling in the workplace, and the value of informing workers of chemical hazards would be greatly reduced. OSHA believes that it has dealt adequately with this issue by setting a threshold level of severity for diseases, signs and symptoms requiring a positive hazard determination (paragraph (gg) (31)).

—The hazard definitions for some Category B hazards are too imprecise, and the science for establishing such hazards is, in any case, presently

inadequate to indicate the existence of such hazards reliably.

OSHA invites comments concerning these criticisms and other issues regarding its categorization of hazards.

d. Specific definitional issues. In selecting the particular Category B (health) hazard definitions contained in the proposed standard, OSHA has made a series of science policy decisions. OSHA believes that identification of the specific science policy decisions involved in each definition will ensure that the scientific issues are fully aired in subsequent hearings. The following discussion is not meant to be exhaustive but, rather, is meant to identify the most important of these issues. The Agency encourages affected parties to identify and discuss additional science policy issues involved in either Category A or Category B hazard determinations.

OSHA invites comment on the following issues of scientific definition, which it regards as particularly noteworthy:

(i) "Highly toxic" and "toxic" substances or mixtures. As noted in the discussion concerning Table 10 (below), several other regulatory efforts have included these hazard categories. The Agency believes that the boundaries it has selected for the two toxicity classes, varying by route of administration, represent a reasonable composite of what other regulatory bodies currently require. However, the Agency invites comments on whether the upper boundaries for each toxicity class should be raised to more nearly approximate the higher values adopted under the Federal Insecticide, Fungicide, and Rodenticide Act (see 40 CFR 162.10(h)(1)).

(ii) "Irritant". The Agency has adopted a somewhat more expansive definition than that used by other agencies in that results of testing in other mammalian species also must be considered in the hazard determination. Other definitions (Table 10 below) have relied only upon data from human and selected mammalian species. The Agency believes that all available data from mammalian species should be used to classify a substance or mixture as an irritant unless such studies utilize inappropriate animal models (paragraph (a)(1)(vi) of Appendix B) or human data of a specified quality establish a lesser risk (paragraphs (c)(3), (5) of Appendix B).

(iii) "Sensitizer". The Agency definition is more expansive than that generally in use for the following reasons:

A. The definition requires consideration of mammalian data as a part of the hazard determination

The Agency believes that this scientific policy since... scientific experience... sensitizers in non... test systems. (Also... under "Irritants"... of non-human... in general).

...requires... substance or mixture... produces an... dynamic reaction in... as well as normal... provision was included to... protection afforded workers... have hypersensitivity... workers are known to be... greater risk of... hypersensitivity reaction to... or mixtures to which...

The Agency believes... appropriate to utilize data... such sensitized individuals... of classifying a... mixture as a "sensitizer".... definition requires a substance... to be classified as a... if the material produces a... reaction. The Agency... at this additional definitional... by the extensive... of this effect for such... drugs.

...". The Agency has... definition contained in its... standard, ... Classification and... of Potential Occupational... (Cancer Policy) (29 CFR... 49 FR 5282, January 22, ... as the OSHA Cancer... the product of an intensive... Agency effort which... the definitional questions, ... is the most appropriate... regulatory purposes.

the Agency recognizes that... hazards identification... would require a conforming... to its Cancer Policy if the... standard is enacted in its... OSHA would issue such a... amendment at the same time... identification standard is... This conforming... would reflect OSHA's... that the labeling of... should be governed by the... process of this... as are the labeling... of other hazards. The... comment on the... of such a conforming

... standard differs from the... in the following ways: ... substance or mixture could be... to be a cancer hazard upon... than that currently required by

the Cancer Policy. In the case of human data, the present standard utilizes case reports (paragraph (b)(3) of Appendix B) and/or formal epidemiologic studies (paragraph (b)(1) of Appendix B) to determine whether a substance or mixture is a carcinogen. The Cancer Policy does not explicitly accept case reports as "suggestive" evidence establishing a substance or mixture as a Category II potential occupational carcinogen. (cf. 45 FR 5044 and 45 FR 5026, January 22, 1980).

B. The carcinogen hazard determination is self-executing under the present proposal while the Cancer Policy specifies that the identification of a carcinogen is one of the issues to be addressed in an individual substance rulemaking (29 CFR 1990.1469)).

C. Under this proposal, Category II potential occupational carcinogens would, without exception, be labeled as cancer hazards, while the Cancer Policy indicates that the need for labeling of Category II carcinogens as such would be determined on a case-by-case basis.

The Agency believes that its present policy position is justified by the following rationale. First, and foremost, a requirement that carcinogen identification occur in the context of an individual rulemaking would preclude the agency from enacting an effective hazard identification standard. The Agency's experience with individual substance rulemakings indicates that for carcinogens, as well as other hazards, it would be well into the next century before current scientific material could be filtered through such hearings. The present proposal's hazard determination process (Appendix A) and evaluation scheme (Appendix B) should provide equivalently accurate results in much less time. Second, there appears to be no sound scientific rationale which would justify treating cancer hazard determinations differently from other health hazards. The Agency invites comments on the elements of this rationale. In addition, the Agency solicits comments on whether the present labeling standard should continue the distinction between Category I and II potential occupational carcinogens contained in the Cancer Policy for purposes of this standard (45 FR 5284, January 22, 1980). The Agency is interested to know whether such a dichotomy would facilitate worker education programs regarding the dangers of carcinogens.

(v) "Reproductive toxin". The definition is based upon objectively ascertainable end results in humans or other mammals. The end results could represent measures of adverse reproductive outcomes which are

commonly accepted by the scientific community. The relevance of such measures to the identification of a human reproductive toxin seems apparent to the Agency. The definition does not require a positive hazard determination based upon *in vitro* evidence such as chromosomal abnormalities, including sister chromatid exchanges, mutagenic assays, or measures of DNA repair. The Agency has presently excluded such evidence from consideration because it is uncertain of the precise clinical significance of such *in vitro* results. The Agency invites comments on whether it should require utilization of such *in vitro* assay results in the final standard.

(vi) "Endangered worker life or caused worker death". This hazard category has been inserted to cover the situation where a substance or mixture has killed a worker or produced serious life threatening illness in workers but where data are unavailable which would permit its classification as "toxic" or "highly toxic."

The Agency anticipates that this hazard category will be particularly useful in the case of mixture hazard determinations. The Agency believes that acute toxicology information permitting mixture categorization as "toxic" or "highly toxic" is frequently unavailable and, as a result, a mixture might avoid a positive hazard determination, were it not for this category.

OSHA anticipates that categorization into the "endangered worker life" category or one of the categories "toxic" or "highly toxic" would be made in addition to the category "other acute, subacute or chronic adverse health effects." There is a need to identify both the former and latter types of hazards on the label in that the former three hazard categories represent immediate lethal or life-threatening dangers which require separate emphasis.

The Agency does not intend that data or reports concerning intentional (self) poisonings be used to determine inclusion in this category, except to the extent that such data or reports reveal pathophysiologic mechanisms relevant to potential actual or emergency working conditions which are not discussed elsewhere.

OSHA invites comments on any perceived ambiguities in the definition of this health hazard.

(vii) "Other acute, sub-acute or chronic adverse health effects." This category, which includes decreased mental alertness and behavior alterations, is expected to generate substantial scientific comment. The category was inserted to reach

documented health effects not otherwise covered. These include such well-documented health effects as erosion of the nasal septum by chromium compounds, intoxication due to involuntary solvent vapor exposures, and liver toxicity from carbon tetrachloride. The Agency believes that potential ambiguities in the scope of coverage have been adequately addressed by restricting the health effects covered to those above a threshold severity (paragraph (g)(31) of the regulation.)

This health effect threshold is meant to be identical to that severity level which should trigger the filing of an occupational illness report under the Occupational Safety and Health Act (Section 8(c)(2) of the Act; 29 U.S.C. 657(c)(2); cf. 29 CFR Part 1904). Though under-reporting of occupational illness is well documented, the Agency believes that the experience gained over the past 10 years by manufacturers and importers in the filing of such illness reports will facilitate their identification of adverse health effects which must be labeled. Moreover, no adverse health effect need be labeled unless the effect has been reported in the scientific literature as described in Appendices A and B.

Thus, the utilization of a two-step inquiry should permit the manufacturer or importer to determine whether a particular adverse health effect is a Category B hazard within the scope of this standard. First, is the adverse health effect one that must generally be reported? Note that actual reporting is not the determining factor in view of documented under-reporting of occupational illnesses. Second, and this is common to all health hazard determinations, is there scientific material documenting the effect (Appendix A) and does such material establish the hazard on a scientific basis (Appendix B)? The Agency believes that rigorous application of this two-step process will resolve any uncertainty surrounding this particular determination.

OSHA does not intend that chemical substances or mixtures which are intentionally ingested over a long period of time in reasonable quantities as part of a normal diet should be classified as producing "other chronic adverse health effects" solely because studies document adverse health effects from immoderate use, e.g., NaCl and hypertension. The Agency solicits comments on whether this interpretation sufficiently clarifies any ambiguities perceived in this hazard category.

In addition, OSHA requests comments on whether an alternative definition for

this hazard category is preferable. In developing the present definition, the Agency considered defining the hazard either in terms of specified pathologic effects, e.g., inflammation, or fibrosis, or by specifying a list of disease outcomes which would trigger labeling. The Agency decided not to adopt either of these alternatives because they were less protective than the one selected.

e. Regulation of Physical Hazards By Other Agencies. A comparison of the scope of physical hazards coverage by OSHA, other Federal regulatory agencies, voluntary industry standards and the European Economic Community (EEC) is provided in Table 9. In general, the definitions are approximately equivalent when various Federal agencies regulate the same hazard.

OSHA based its physical hazards definitions on the voluntary industry standards developed by the American National Standards Institute (ANSI) so that there are only minor discrepancies in scope of coverage. There are more discrepancies between OSHA's physical hazard definitions and comparable definitions developed by the EEC.

During the course of this standard's comment period, the Agency will make an effort to harmonize the minor inconsistencies, largely involving test procedures, among Federal agencies. A more intensive harmonization effort between OSHA and EEC appears to be required and OSHA expects to participate in such an effort, together with other affected United States agencies.

Table 9.—Comparison of Scope of Coverage of Physical Hazards by U.S. Regulatory Agencies, European Economic Community and American National Standards Institute

OSHA physical hazards (Category A) 29 CFR	DOT 49 CFR	CPSC (FHSA) 16 CFR	EPA (FIFRA) 40 CFR	ANSI Z 129.1- 1976	EEC 79/631/ EEC Article 2
Corrosive material.....	173.240(a), (b) similar.	1500.3(b) (7), (c)(3)...	162.10(h) (Category I) similar.	(2) Similar.....	(i) Similar.
Extremely flammable liquid.....	NRS (see flammable material).	1500.3(b) (10), (c) (6)(3) similar.	162.10(h)(2)(iii) S.	(2) S.....	(c), (d) S.
Flammable material.....	NRS (see flammable gas).	1500.3(c) (6)(i) 1500.3(c) (6)(ii)	162.10(h) (2)(ii) similar.	NSC (see flammable gas).	NC.
Aerosol.....				(2) S.....	(d) Similar.
Gas.....	173.300(b) similar.....	NRS (see flammable).	NRS.....	(2) S.....	(a) (includes combustibles) M.
Liquid.....	173.115(d) S 173.115(a) similar.	1500.3(b) (10), (c) (6)(i) similar.	162.10(h) (2)(iii) (includes combustibles) M.	(2) S.....	(d) Similar. NRS (see flammable liquid).
Solid.....	173.150M.....	1500.3(c) (6)(iii), (iv).	NC.....	(2) S.....	(d) Similar.
Combustible liquid.....	173.115(b) S.....	1500.3(b) (10) M.....	NC.....	(2) S.....	(b) Corresponds to OSHA definition for reactive material.
Pyrophoric material.....	173.115(c) S.....	NC.....	NC.....	(2) S.....	(d) Similar.
Strong oxidizer.....	173.151 S.....	NC.....	NC.....	(2) Similar.....	(b) Corresponds to OSHA definition for reactive material.
Reactive material.....					
Explosive material.....	173.50S.....	1500.3(c) (7)(i) (A) M		NC.....	(a) Similar.
Organic peroxide.....	173.151(a) S.....	NC.....		NC.....	NC
Pressure-generating.....	NC.....	1500.3(c) (7)(i) (b), (C) M.		(2) S.....	NC
Water-reactive.....	NRS (see flammable solid).	NC.....		NC.....	(d) M.
Compressed gas.....	173.300(a) similar.....	1500.3(c) (7)(i) (D) M	162.10 (iii) M.....	(2) S.....	

NOTE.—Reference is OSHA Standard; S = Same coverage; M = OSHA more inclusive; L = CSHP; less inclusive; NRS = Not regulated separately; NC = No Category.

f. Regulation of Health Hazards By Other Agencies. Table 10 provides a comparison of the efforts of Federal agencies, ANSI and EEC to define health effects for the purposes of labeling regulations. All the organizations listed define and regulate all or most of the first four health hazards listed (highly toxic, irritant, sensitizer). Manufacturers

and importers thus should be able to utilize their organizational experience in complying with the OSHA standard, though they must still perform the required OSHA hazard determination process. OSHA is particularly interested in comments which would lead to a harmonization of definitions among the various agencies involved. OSHA

expects to participate in international efforts aimed at harmonization in this area.

Regulatory experience with the remaining health effects that OSHA proposes to cover in this labeling standard is substantially more limited (see table 10). However, OSHA does not believe that lack of substantial regulatory experience by other organizations concerning carcinogens, reproductive toxins, and the categories involving endangerment to human life and other adverse health effects should preclude OSHA's regulatory effort concerning these health effects. OSHA believes that the validity of the scope of hazards covered in this standard should be judged solely on whether the scope of hazards regulated corresponds to the scope of hazards which the worker

faces. OSHA further believes, on the basis of its accumulated expertise in the development of health standards, that the current consensus among occupational physicians, industrial hygienists, toxicologists and other health personnel is that workers face hazards in all the health effects categories defined. Moreover, the agency does not believe that the technical problems involved with defining or identifying carcinogens or reproductive toxins are inherently more difficult than those involved with sensitizers and irritants, two health effects which have been extensively regulated. The Agency would benefit from an exchange of ideas in this area between government, academic, labor and industry witnesses in the course of extensive rulemaking proceedings.

manufacturer or importer need only evaluate material contained either in the National Library of Medicine's Toxicology Data Bank (TDB) or in a representative selection of standard reference works or relevant NIOSH documents (See App. A paragraph (b)(1)). In addition, the manufacturer or importer may use any other relevant data (paragraph (b)(1)(ii)). The manufacturer or importer is not required to undertake a literature search (paragraph (c)). The evaluation is to be based upon sound scientific judgment (paragraph (b)(3)) and the formal evaluation scheme described in Appendix B is not required.

OSHA believes that an abbreviated hazard determination process for Category A hazards is adequate to determine whether the substance possesses the physical properties specified in the Category A definitions. The data sources required are sufficient because the physical properties are based upon standardized physical or chemical tests which ordinarily demonstrate rather small variations in results, if performed as specified. Analogously, there is no need for an extensive evaluation scheme since there is widespread professional agreement on the interpretation of such test results.

In contrast, the hazard determination process for Category B hazards for substances is more extensive, both in the scientific sources which are required to be consulted and the evaluation scheme to be applied. In addition to the sources required to be consulted for Category A hazard determinations, the manufacturer or importer is required to undertake a literature search using specified computerized data files, to obtain copies of the scientific studies so identified, and to evaluate such material using the scheme set out in Appendix B of the proposed standard (paragraph (c)). In addition, a manufacturer's or importer's in-house health effects studies must be evaluated by the Appendix B scheme (paragraph (c)(1)(ii)). A manufacturer or importer need not evaluate search material or in-house health effects data for a particular health hazard, if he or she has elected to label the substance for the hazard based upon the TDB, standard reference works or NIOSH documents (paragraph (c)(1)).

Category B substance hazard determinations are necessarily more extensive than those required for Category A hazards because health effects studies involving animals or humans yield substantially more variable results than do purely physical

Table 10.—Comparison of Scope of Coverage of Health Hazards by U.S. Regulatory Agencies, European Economic Community and American National Standards Institute

OSHA health hazards definitions (Category B) 29 CFR	DOT 49 CFR	CPSC (FHSA) 16 CFR	EPA (FIFRA) 40 CFR	ANSI Z129.1-1976	EEC 79/831/EEC Article 2
Highly toxic.....	Poisons "B" 173.343 Similar.	1500.3(b), (6), (c) (1) Similar (But see "Endangered Life," "Other Adverse Health Effects" below).	162.10 (h) (1) (Category I)S.	(2)M.....	(f) Similar, qualitative definition.
Toxic.....	NC.....	1500.3(b) (5), (c) (2) Similar.	162.10(h) (1) (Category II).	(2)M.....	(g), (h) qualitative definition.
Irritant.....	173.381 Different.....	500.3(b)(8), (c) (4)S.	162.10(h) (1) (Categories II-IV) Similar.	(2)M.....	(j) Similar.
Sensitizer.....	NC.....	1500.3(b) (9), (c) (5)M.	NC.....	(2)M.....	NC.
Carcinogen.....	NC.....	NC.....	162.11(a) (3) (ii) (A) Similar Rebuttable Presumption against registration.	NC.....	(1) Similar- imprecise definition.
Reproductive toxin.....	NC.....	NC.....	Same reference as carcinogen.	NC.....	(m), (n) Undefined.
Endangered worker life.....	173.326 Poison "A" Similar.	1500.3 (c) (1) (f).....	162.1(a) (3) (i) M Rebuttable presumption against registration.	NC.....	NRS (see highly toxic and toxic).
Other adverse health effects.....	NRS (see highly toxic).	NC.....	162.1(a) (3) (ii) (B) M Rebuttable presumption against registration.	NC.....	NRS (see toxic).

NOTE.—Reference is OSHA Standard S—Same coverage; M—OSHA more inclusive; L—OSHA less inclusive; NRS=Not regulated separately; NC=No category.

3. Hazard determination process. a. Description. The hazard determination process is described in Appendix A of the proposed standard. (References in this section of the preamble are to Appendix A). A manufacturer or importer must utilize this process in determining whether a substance is

hazardous. However, the extent to which the process is applicable varies depending upon whether a substance is being evaluated as a Category A (physical) hazard or Category B (acute or chronic health) hazard.

To determine whether a substance poses a Category A hazard, the

or chemical determinations and the interpretation of such results calls for more professional judgment. The Category B hazard determination process will ensure that the results of substantially all relevant scientific studies involving a substance are considered. Moreover, the Appendix B evaluation scheme should ensure uniform judgment outcomes based upon what the Agency believes is a sound scientific approach.

The present hazard determination process would not normally apply directly to mixtures. Mixtures are deemed to represent the same hazards posed by their constituent substances, with some qualifications (paragraph (i) of the standard). A similar assumption has been used by the European Economic Community in its directives (regulations) governing the labeling of preparations (mixtures) (73/173/EEC, 77/728/EEC, 78/631/EEC). If a manufacturer or importer is dissatisfied with the results of a hazard determination based upon its constituent substances, he is free to test the mixture. Of course, if a mixture has been evaluated for a particular hazard, then the manufacturer or importer must use his or her sound scientific judgment to determine whether a Category A hazard is present (paragraph (b)(3)) or the Appendix B evaluation scheme to determine whether a Category B hazard is present (see, in particular, paragraph (c)(5) in Appendix B). The proposed standard would not, however, require that a manufacturer or importer perform a literature search for mixture hazard determinations because OSHA believes that the yield from such searches would not justify the required expenditures of time and money. This belief is based upon a professional judgment that the scientific literature reflects a strong preference of epidemiologists and toxicologists for analyzing the properties of substances, rather than mixtures.

Thus, in view of the complexity inherent in Category B hazard determinations, the proposed standard provides assistance in the form of explicit directions to the manufacturers or importers. The standard describes the hazard determination process (Appendix A), details the materials (including the output of a required literature search) that must be used for the determination (Appendix A) and provides an evaluative scheme for such materials (Appendix B). The Agency believes that the explicit directions for compliance just described will reduce the ambiguities inherent in a less detailed standard, will facilitate compliance and result in many fewer enforcement actions. Moreover,

specification of the Category B hazard determinations process is required to obtain uniformity of labeling.

b. Performance vs. specification standard for the hazard determination process and evaluation scheme. Some industry sources have objected to the approach taken in the proposal. They advocate a "performance" standard under which manufacturers or importers of a chemical would be free to determine the existence of a defined hazard by whatever procedures they consider appropriate.

These industry sources claim that there are alternatives to the hazard determination (Appendix A) and evaluative procedures (Appendix B) OSHA has chosen which are just as reliable. They also claim that these are presently in use, and that it therefore makes no sense to require firms to shift to the procedure OSHA prefers.

However, those making these claims have not, to date, actually described the procedures which might function adequately as alternatives to the procedures of the proposed standard. Nor have these sources informed OSHA of the hazard determination and data evaluation procedures presently employed by any particular firm. Consequently, OSHA presently has no information which would substantiate the claim that a performance standard is appropriate.

OSHA believes that it is appropriate and necessary to establish the quantity and quality of scientific evidence required in the hazards determination process. A performance standard would simply not guarantee that any firm would utilize an appropriate alternative to the hazard determination and evaluation procedures of the proposed standard. Under a performance standard, every firm would be free to utilize any procedure, or no procedure at all, to determine hazards.

Moreover, the enforcement mechanisms at OSHA's command are simply inadequate to protect against the very real possibility that under a performance standard a substantial number of firms might utilize procedures which are scientifically deficient or inconsistent to identify the hazards of workplace chemicals. There are thousands of chemicals which are manufactured in, or imported into, this country. Yet, OSHA has at its disposal only approximately 1500 inspectors, whose duties encompass enforcement of all requirements imposed by OSHA in the workplace. Obviously, in terms of total numbers and the considerable responsibilities already incumbent upon these inspectors, this inspection force would be utterly inadequate to ensure that each manufacturer and importer

subject to the standard employed a reliable procedure to determine hazards.

OSHA is willing to consider reasonable alternatives to its proposed evaluation procedures. OSHA is also willing to offer the choice of a number of scientifically sound procedures, if they exist. Accordingly, OSHA solicits comments on these issues. Following comment, should OSHA choose to move to a performance standard, the agency may adopt Appendices A and B as recommended rather than mandatory procedures.

c. Literature Search. 1. OSHA has made a concerted effort in the course of revising earlier drafts to ensure that the search requirement is technically feasible. As a consequence of extensive discussion, and based upon sound science policy grounds, the Agency has decided not to include a search requirement for mixtures (paragraph (a)(2) of Appendix A), to permit manufacturers and/or importers to undertake hazard determinations jointly to the extent permitted by law (paragraph (a)(3) of Appendix A), and to extend compliance times for small manufacturers and importers (paragraph (ii)(1)(ii) of the standard). The delay in compliance dates for small manufacturers and importers will permit them to rely on hazard determinations of larger manufacturers or trade groups (paragraph (ii)(1)(ii) of the standard) by obtaining copies of their labels from a national label repository (subsection (w) of the standard).

The mandated literature search for Category B hazard determinations (paragraph (b)(2)(ii)(C) of Appendix A) appears well within the current search capability of existing computerized information services.

The following analysis, based upon material submitted in compliance with the Toxic Substances Control Act Inventory requirements (40 CFR Part 710), indicates that the present standard will impose a one (1) time increase in search requests of some 250,000.

Table 11.—TSOSCAI Substances (33)

Number of companies reporting a substance	per cent of TOSCAI inventory	Number of substances reported (approximate)	Maximum of average number of companies reporting a substance	Estimated number of searches
— 4	90	49,500	2.5	123,750
5-9	6.3	3,465	7	24,255
— 10 (x = 30)	3.7	2,035	30	61,050
Total				229,055

The estimate has been adjusted upward from that in the table to provide for search requests involving the other substances not on TOSCAI which must be evaluated (paragraph (d) of the standard). Taken together, such other substances contribute a comparatively small number to the total. The Agency wishes to stress that this is a "worst case" estimate in that the estimate has not been reduced to reflect the probable impact of joint evaluations or reliance on the national label repository in lieu of a search (paragraph (w) of the standard and paragraph (a)(3) of Appendix A).

On the supply side, OSHA understands that the recent expansion of the computer facilities for MEDLARS^(R), only one of the available computerized information services, has substantially increased search capacity. The August, 1980, search load of some 60,000 searches appears to represent less than half of the system's monthly capacity (Phone communication, NLM, 1980).

Thus, the Agency concludes that the literature search requirement is technically feasible. OSHA invites comments on the related issues of whether searches may be delayed in various regions because of a dearth of trained information system users and whether some manufacturers or importers lack access through inter-library loan programs to duplicates of the scientific material identified in the search.

While OSHA believes that the expansion of existing commercial information services will prevent any serious compliance problems in this area, the Agency intends to explore additional mechanisms for complying with the search requirement. Among the additional mechanisms under consideration are permitting reliance on duplicate copies of current searches (thus avoiding the actual search) with payment as appropriate and exploring creation of a central duplicating service for search materials. The Agency may, in addition, extend compliance dates if rulemaking comments so indicate.

d. *Use of TDB, standard reference works and NIOSH documents.* OSHA believes that TDB (paragraphs (b)(1) and (c)(1) of Appendix A), the NIOSH documents (paragraphs (b)(1)(i)(B) and (c)(1) of Appendix A), and the standard reference works (paragraphs (b)(1)(i)(A) and (c)(1) of Appendix A) are essential elements of the hazard determination process. All these

materials have been subject to scientific peer review and thus represent unusually reliable sources of scientific information. OSHA invites comments on whether alternative data sources should be considered.

The Agency does not, however, believe it would be productive in the rulemaking to urge consideration of a particular text not on the list of standard reference books, "Source Used to Prepared Toxicology Data Bank Records" (paragraphs (b)(1) and (c)(1) of Appendix A). Additional texts can already be used in determining whether a Category A hazard is present under paragraph (b)(1)(ii) of Appendix A. In the case of Category B hazard determinations, unrestricted expansion of the standard reference book list beyond that determined by the TDB expert scientist group would certainly cloud the compliance responsibility of the manufacturer or importer without necessarily improving the hazard determination process. OSHA believes that a current standard reference book list, developed by an expert committee, represents the most reliable list for the limited purposes for which it is intended, i.e., positive hazard determinations in the case of Category B hazards are ultimately dependent on evaluation of scientific studies and not on reference book content, unless the manufacturer or importer chooses to rely on the standard reference book (see paragraph (b)(2)(iii)). The standard provides for modification of the list.

e. *Search files.* The Agency also invites comments on the particular data files required for the literature search (paragraph (c)(1)(ii) of Appendix A) and whether equivalent alternative data files are available. CANCERLIT^(R) is required because it is a unique source of information on the National Cancer Institute's carcinogen bioassay program. OSHA specifically invites comment on the extent of duplication resulting from the use of the three remaining data files: MEDLINE^(R), TOXLINE^(R) and RTECS.

The Agency requires all three data files be used because it is current scientific practices to include all three in routine searches. Comments are also invited on the need for any additional data files. The Agency is aware of only the Excerpta Medica information file as a possible alternative but invites comment on this issue.

f. *Concentration of Constituent Substances and Mixtures Hazard*

Determination. The proposed standard sets threshold limits for concentrations of hazardous substances in mixtures, above which, except in certain defined circumstances, such substances, and the mixtures in which they appear, are regulated by the standard. For non-carcinogens, the threshold value is at least 1.0% (by weight) of a mixture. For carcinogens, the threshold value is at least 0.1% (by weight) of a mixture (see paragraph (i)(2) of the standard).

OSHA believes that the uniform thresholds it has chosen are appropriate, and that the use of a uniform threshold is integral to the generic approach to regulation which the hazard identification standard embodies. Elimination of any threshold would greatly burden the hazard determination process and likely render it infeasible. On the other hand, adoption of a system which required the establishment of an individual threshold value for each substance, case by case, would in OSHA's view render the standard impossible to administer and enforce. There may, however, be acceptable formulas, taking account of the variables of potency and concentration, which can be applied reliably to determine whether constituent substances and the mixtures in which they appear should be regulated as hazards (see EEC directives for labeling mixtures 73/173/EEC, 77/728/EEC and 78/631/EEC). OSHA invites comments on this possibility and other issues germane to the threshold percentage exclusion question.

4. *Evaluation Procedure. a. In General.* The proposal mandates that a substance or mixture be classified as a Category B hazard, if the proprietary in-house studies or the studies identified in the literature search satisfy the following criteria:

1. The study is either "adequate and well-controlled" (paragraphs (a)(1) and (b)(1)(2) of Appendix B) or represents an acceptable "case report" (paragraphs (a)(2) and (b)(3) of Appendix B); and
2. The study establishes a "statistically significant" (paragraph (a)(6) of Appendix B) relationship between exposure to the substance and the subsequent occurrence of a covered hazard or "strongly suggests" such a relationship (paragraph (b)(3) of Appendix B); and

3. The relevant study conclusion is accepted by any subgroup of qualified experts (paragraph (b)).

OSHA believes that this hazard determination process and its

evaluation procedure represents the sequence and content of any inquiry that a reasonable and prudent modern scientist would undertake to determine whether a chemical is a Category B hazard. The evaluation procedure does not consider anecdotal material because the Agency does not believe that such "data" warrant a positive hazard determination under this standard. Nor does the evaluation procedure consider expert opinion evidence based upon structure-function or stereo isomer relationships. Although the Agency believes that such opinion evidence may be too problematic to warrant labeling, it invites comments on this point.

b. *Adequate and Well-controlled Study.* The definition of an "adequate and well-controlled" study is based upon the Epidemiology Work Group's "Draft IRLG. Guideline for Documentation of Epidemiologic Studies" (34). The definition has been modified to meet the proposed standard's need to define a minimal set of criteria for evaluating studies that have already been performed. Consequently, while OSHA recognizes that some of the elements that have been dropped from the present definition would have enhanced the utility of some of the scientific studies that will be evaluated under this standard, their omission should not preclude consideration of such studies. The Agency invites comments on whether additional study elements should be required.

In addition, an alternative route of identifying an "adequate and well-controlled study" was provided to ensure that past studies which have achieved general professional acceptance would be considered in the evaluation. The Agency believes that publication of a study in a "peer review" journal (paragraphs (a)(1)(vii) and (a)(4) of Appendix B) provides sufficient scientific credibility as to warrant the standard's requirement that it be considered in the evaluation process. Such studies must still demonstrate "statistical significance" and be accepted by a subgroup of experts to warrant a positive hazard determination.

The Agency requests comments on its determination that a single adequate and well-controlled study shall trigger a positive hazard determination. In coming to this conclusion, OSHA weighed the possibility that there would be some false positive hazard determination under this approach, i.e., positive studies later invalidated,

against the certainty that workers would experience prolonged exposures to hazardous chemicals if confirmation were required. NIOSH indicated the following periods required to complete a second study, assuming it is begun after the first study becomes available:

Table 12.—Completion Times for Various Types of Epidemiologic Studies

Types of study	Average time to completion (years)
1. Retrospective cohort mortality studies.....	13.9
2. Health hazard evaluations.....	.83
3. Case-control studies.....	.5

¹ Ten in period 1978-80.

Source: Personal communication from Mr. Richard Lemen, NIOSH, 1980.

Of course, this table seriously underestimates the actual duration of continued exposure. The capacity of the scientific community to undertake major epidemiologic studies is limited. Therefore, considerable time may elapse before a confirming study may even be begun. In view of the extraordinary shortage of trained epidemiologists and toxicologists, delays in undertaking studies will likely be substantial.

c. *Case Studies Use.* The proposed standard requires reliance on well-documented case studies (paragraphs (a) (2) and (b) (3) of Appendix B). OSHA believes that such studies should serve as a basis for a positive hazard determination, e.g., vinyl chloride monomer exposure and resultant hemangiosarcoma. In response to a request from OSHA, NIOSH investigated two relevant issues: 1) the historical utility of case reports and 2) the current utility of case reports that would be generated from the required literature search. OSHA invites comments on the issue of reliance on case reports for Category B hazard determinations. The following are summary tables:

Table 13.—Historical Utility of Case Reports—Selected Examples

I. Substances first identified by case reports in occupational settings which are now widely accepted as hazardous to health	
Hydrogen Sulfide	
Methyl Alcohol	
Carbon Disulfide	
Nitrogen Oxides	
Asbestos	
Benzene	
II. Hazardous substances called to attention following case reports of occupational exposure but for which preliminary animal data existed	
Vinyl Chloride	
Bis (chloromethyl) ether	
DBCP (dibromochloropropane)	

Table 13.—Historical Utility of Case Reports—Selected Examples—Continued

III. Hazardous Substances first identified as carcinogens by case reports of occupational exposures which have been supported by epidemiological studies	
Chromium	
Nickel	
Arsenic	
Benzene	
IV. Hazardous Substances first identified from case reports of occupational exposure which have not been addressed by epidemiological studies	
DMAPN (dimethylaminopropionitrile)	
Sodium Hydroxide	
V. Substances first identified as hazardous by case reports which were later discredited by epidemiological and/or animal studies	
Aniline	
Fibrous Glass	
Hair Spray	

Table 14.—An Assessment of the Appropriateness of the Use of Case Reports for the Determination of a Hazard

	Number of case reports published	
	1980-1978	1977-1966
Case reports reviewed (5% sample).....	10 (100%)	14 (100%)
Causal relationship sufficiently established.....	8 (80%)	11 (79%)
Reported situation amenable to labeling.....	7 (70%)	10 (71%)
Reported situation possibly covered by the standard proposed by OSHA.....	8 (80%)	7 (50%)
First indication of the hazard.....	3 (30%)	4 (29%)
Based Only on the Case Reports Which Were the First Indication of the Hazard		
Causal relationship sufficiently established.....	3 (100%)	3 (75%)
Reported situation amenable to labeling.....	2 (66%)	3 (75%)
Reported situation possibly covered by the standard proposed by OSHA.....	2 (66%)	3 (75%)
May possibly indicate labeling is appropriate.....	2 (66%)	1 (25%)

Source: Personal communication from Mr. Richard Lemen, NIOSH, 1980.

The Agency believes that these data clearly support the necessity for including case reports as one basis for a positive hazard determination, especially in view of the probable difficulty in mounting epidemiologic studies to confirm the case reports. The Agency invites comments on the advisability of its decision to require utilization of case reports.

d. *Statistical Significance.* The significance level has been set at 0.10 rather than the customary 0.05 level (paragraph (a)(6) of Appendix B). While the increased Type I error results, by definition, in an increase in false positive hazard determinations, there will be a corresponding decrease in false negative determinations. While the Agency believes that this is an appropriate strategy for a preventive

health standard, it recognizes that the significance level chosen is non-traditional and invites testimony addressed to this issue.

Testimony is also invited on the related question of whether the criteria which govern the use of inconsistent data are advisable (paragraph (c) of Appendix B). For example, the power (0.89) of data to detect a hazard of a specified magnitude (25% increase in risk) is consistent with that of the Cancer Policy (29 CFR 1990.144 (a), 1980). However the magnitude of the risk that must be detectable by the negative study has been decreased from 50% to 25%. The Agency believes that, given data or studies that indicate a potential hazard, the worker should be informed of the potential hazard unless extremely reliable negative data are available.

e. Expert Opinions. The final element of the data evaluation scheme requires that a substance or mixture be classified as a hazard if a subgroup of experts accepts the conclusion of statistical significance for results in an adequate and well-controlled study (paragraph (b)(1) of Appendix B) or accept the cause-effect relationship demonstrated in case report(s). This acceptance may be manifested in a variety of ways and a rebuttable assumption of such acceptance is established when at least one qualified independent expert has endorsed the results (paragraph (d) of Appendix B).

The Agency understands that this position regarding the role of experts is different from that which prevails in the course of adjudication. However, as a matter of policy, OSHA believes that labeling a substance or mixture as a hazard should not require support from the majority of experts. Such an *ad hoc* choice of consultants does not guarantee that the entire spectrum of professional opinion is adequately represented. Rather, the Agency believes that a substance or mixture should be classified as a hazard if evidence of the specified quality is available, two or more experts (including the author) concur in the conclusion that a hazard is present, and strong evidence to the contrary is not available at the time of hazard determination (paragraph (d) of Appendix B). The Agency invites comments on this approach.

C. Regulatory Issues

1. "Performance" vs. "specification" requirements. As previously stated in the discussion of hazard evaluation procedures, OSHA believes that employers should be required to follow specified procedures where established scientific principles are applicable.

OSHA is not opposed, however, in appropriate technical areas, to setting goals ("performance" standards) and allowing employers to reach those goals by whatever means they consider practicable. For instance, the proposal sets performance standards for labeling piping systems (paragraph (i)) and labeling continuous operations (paragraph (i)(3)). OSHA will consider performance standards in other areas where it can be shown that specifying particular procedures is unnecessary, and invites comment on this issue.

2. Content and format of labels and placards. The proposed standard would require chemical identification and hazard warning information on labels and placards for hazardous chemicals. This is because OSHA believes that labeling is the most immediate and reliable way of communicating hazard related information to workers.

Some industry representatives have expressed concerns about this requirement. They believe that it will be difficult to include all required information in readable form on normal size labels. There have also been suggestions from both industry and representatives of workers that the hazard warnings set out in Appendix C are either too comprehensive or not comprehensive enough. OSHA invites comments upon all aspects of the label format requirements of the proposed standard. OSHA also invites alternative proposals for labeling format.

As previously stated, the requirement for disclosure of chemical identity is closely related to the trade secrets issue. Some industry representatives have suggested that confidentiality for trade secrets might be enhanced if chemical identity of hazardous materials were maintained in reference books stored centrally and made available to workers upon request. In this way, employers could keep track of those receiving potential trade secret information and require confidentiality agreements from those to whom trade secret information is disclosed.

Advocates for workers have opposed this alternative to labeling on several grounds. First, it is cumbersome. The worker must make a request to see information he or she wishes to check. Second, the worker must leave the work area in order to check such information. Third, the employer knows which employees are making requests concerning the identity of hazardous materials, and unions fear this may lead to reprisal and harassment. OSHA invites comment on whether possible enhancement of confidentiality afforded by a reference book system outweighs

the drawbacks of removing a requirement for workplace labeling.

3. Disclosure of chemical identity in labels shipped in commerce. A closely related issue involves the inclusion of CAS numbers on labels being shipped downstream to industrial users. The proposed standard requires that labels indicating the chemical identity (the CAS number) of hazardous chemicals be placed on containers before being shipped downstream to workplaces where such substances and mixtures will be used (paragraph (o)). Industry representatives have stated that this requirement will only compound the trade secrets problem because the identity of hazardous trade secret chemicals will be open to scrutiny, not only in workplaces, but in commerce to other employers who may be competitors. Worker representatives have countered that without a requirement that labels be in place when containers reach a downstream workplace, there is no certainty that containers of hazardous materials in downstream workplaces will be speedily and accurately labeled.

The proposed policy to require labeling before hazardous materials are shipped is grounded on several preliminary conclusions. OSHA has concluded that once manufacturers and importers are required to disclose the chemical identity of hazardous substances to both their own employees and the employees of downstream users, the incremental damage to confidentiality caused by requiring chemical identification to appear on labels in commerce is relatively inconsequential. OSHA has also concluded, in the absence of evidence to the contrary, that there is a substantial possibility for tardy and inaccurate labeling if labels are not required to be in place upon arrival at a downstream workplace. OSHA invites comments on these points.

4. Exclusion of small containers. The proposed standard provides for certain exemptions from labeling requirements applicable to containers of hazardous materials in the workplace (paragraphs (u)(i), (g)(12)). Of particular concern may be the exemption for containers of 5 gallons (19 liters) or less in volume which are used to transfer hazardous materials from one container to another in a particular work area. OSHA requests comments concerning the sizes and purposes of containers which should be exempted from labeling requirements.

5. Access to records and documents required by the standard. The proposed standard would provide access to a number of types of records and

documents by workers, their designated representatives, their unions, and OSHA and NIOSH (paragraphs (cc) and (dd)). In addition, the standard requires manufacturers and importers to maintain separate files containing the materials relevant to the hazard evaluation for each substance and mixture they produce or import (paragraph (m)). The material in these files is to be made available on request to employees and former employees in work areas where the substance or mixture is or was present (paragraph (dd)). In the event a firm goes out of business, the standard provides for the transfer of documents and records to NIOSH (paragraph (ee)).

OSHA believes that maintenance of the specified documents and records is essential to the ability of workers to protect themselves from workplace hazards for several reasons. First, these documents and records may provide important information relevant to chemical hazards which is not required to be on labels. Second, access to the materials upon which a manufacturer or importer bases hazard evaluations provides workers and their representatives the means to verify the determination made. Likewise, these materials provide OSHA with the ready documentation intrinsic to efficient enforcement of the standard.

The benefits of the access and record keeping provisions of the standard must be weighed against the burdens these provisions will impose upon importers, manufacturers, and industrial users. Information presently available to OSHA indicates that in some workplaces at least some of the material covered by the access and record keeping provisions of the standard is presently made available. Whether filing systems similar to those proposed by the standard are in general use is less clear.

Comments on a number of issues would be helpful to OSHA in making a judgment as to the adequacy of its proposals concerning access and recordkeeping. These include:

The nature of the burden these provisions will place upon industry, with particular reference to existing industry practices in the access and recordkeeping areas;

The use to which information to which access is provided by the proposed standard will be put by workers and their representatives;

Whether employers who use chemicals should be entitled to inspect the records and documents of manufacturers and importers pertaining to those chemicals;

Whether the classes of persons and groups to whom access to records and

documents are granted should otherwise be expanded or limited; and

Suggestions for any alternative access and record keeping mechanisms which would reduce the burden on industry, or make access to information by workers easier or more efficient.

6. Worker access to safety data sheets. The proposed standard would provide material safety data sheets (if they exist) to workers upon request. There is no requirement that an employer affirmatively make copies available to each worker in the workplace. This provision is intended to minimize the administrative burden upon employers of providing copies in every work area.

Representatives of workers have objected to such a provision, claiming that to require workers to request these documents will leave workers open to employer harassment and discrimination. These representatives would prefer that copies of relevant material safety data sheets be posted in each work area. They also suggest that additional copies be made available in work area locations where they can be picked up without a specific request. Finally, these representatives have stated that worker health and safety requires that these documents be available for immediate inspection on the job where necessary.

OSHA does not have before it specific evidence that would justify the allegation that workers who request documents will be harassed or discriminated against. Nor does OSHA have before it evidence of the need for material safety data sheets to be immediately available on the job. OSHA invites comments on these issues.

7. Material safety data sheets. The proposed standard requires that, where available, copies of material safety data sheets (MSDS) for hazardous substances and mixtures be given to workers and their representatives upon request (paragraph (cc)). The proposed standard does not, however, require that manufacturers and importers of hazardous substances and mixtures produce an MSDS for each hazardous substance and mixture. Nor does the proposed standard define the content of any MSDS a manufacturer or importer decides to produce (see the definition of an MSDS in paragraph (gg)(29)).

OSHA chose to impose neither of these requirements because, under the proposed regulation, the MSDS is not the primary vehicle for communicating essential hazard related information to workers. On this assumption, to have imposed such requirements would have put a large and unjustifiable burden upon industry.

OSHA invites comments on whether the MSDS should play a more prominent role than presently contemplated in the information system proposed under the hazard identification standard. If so, OSHA also invites comment on whether a MSDS should be produced under some defined format for every hazardous substance and mixture to be used in the workplace.

8. Substance-employee identification lists. In developing this proposal, OSHA very seriously considered requiring manufacturers and industrial users to develop substance-employee identification lists for each work area. Such lists would provide a cross-reference between the hazardous chemicals present in a given work area and the identities of the employees working in the area.

The purpose of such a listing requirement would be to give workers an overall picture of the hazardous chemicals present in the areas in which they work, and which might, therefore, adversely affect their health. If required to be preserved for extended periods of time, e.g., 30 years, these lists would also provide an accurate record of potential chemical exposures affecting a worker over time, although the lists would not establish quantitative levels of exposure. This information, in turn, could provide epidemiologists valuable assistance in tracking down potential sources of occupational disease.

The costs and administrative burden connected with the creation and long term preservation of substance-identification lists would not be insubstantial. Yet, as the Regulatory Analysis of the proposed standard shows, a requirement for such lists may well yield results which dramatically increase the benefits of the hazard identification in terms of improved worker health and safety over time.

OSHA did not include a requirement for the development and preservation of substance-employee identification lists because while they potentially would establish a record of basic evidence essential to determining the effects of hazardous chemicals with precision, the extent of the burden they would impose upon manufacturers and industrial users is not yet clear. In particular, OSHA is uncertain about the burden development and maintenance of such lists would place upon downstream users of chemicals, such as automobile manufacturer, whose operations tend to be labor-intensive and to use thousands of chemicals. This type of industrial structure would obviously compound the difficulty of tracking and cross-referencing chemicals and employees, but to what degree is unknown. On the

other hand, these employers, as well as others, may now have in place systems for keeping track of chemicals and employees which might be adapted to the same use as substance-employee identification lists, or might at least reduce the burden of putting substance-employee identification lists in place.

Accordingly, to determine whether a requirement for substance-employee identification lists should be incorporated in the final standard, OSHA invites comment upon the uses to which workers, their representatives, governmental agencies, and medical researchers would put the information provided by substance-employee identification lists. OSHA also invites comments upon the burden which compilation of such lists would impose upon industry, with particular reference to the extent industry presently compiles and maintains similar information.

9. *The need for generic training requirements.* The proposed standard does not include any requirement that workers be trained to use the hazard identification information communicated to them. This is not because OSHA believes that training is unimportant to the overall effort to make workplaces healthful and safe. It is because OSHA sees the communication of hazard-related information and worker training as distinct tasks which are not necessarily interdependent for the provision of meaningful benefits. Thus, although the usefulness of hazard related information would undoubtedly be enhanced by appropriate training, such information is extremely helpful to workers in and of itself. Moreover, OSHA is aware that some employers already provide employees with adequate training in hazard identification.

Furthermore, OSHA believes there is a major advantage in creating a comprehensive communication and training system in several stages. This procedure minimizes the burdens upon industry by spreading cost and effort over time, while still providing substantial benefits to workers with the promulgation of each component of the overall system. OSHA believes this to be a sound approach, and comment on this view is invited.

10. *Impact on small business.* OSHA recognizes that the proposed standard may impose greater burdens on small business than it does on large firms. For example, as mentioned, some large chemical manufacturers have indicated that they already follow chemical evaluation procedures similar in scope to those proposed in the standard. Consequently, the burden in additional

cost and effort which implementation of the standard would impose such firms is less than that upon smaller firms which have no such procedures in place.

The proposed standard attempts to minimize the differential burden upon large and small firms by establishing a repository for hazard warning information and by delaying the dates by which small manufacturers and importers must complete evaluation of chemicals they produce or import (paragraphs (w) and (ii)). The repository for hazard warning information will contain all information relevant to the results of the hazard evaluation for any chemical. This information will be available to manufacturers and importers. Delaying the compliance dates for small manufacturers and importers will allow them to utilize the hazard evaluations made by large manufacturers or importers for chemicals they also produce or import.

There may be other provisions which would ease the burden upon small business without sacrificing the comprehensiveness and accuracy on which the hazard identification standard relies to help protect worker health. OSHA invites comments and suggestions regarding these.

11. *Miscellaneous issues.* Finally, there are several specific issues upon which comment in response to publicly released preliminary drafts has been sparse, but which may be controversial. Accordingly, OSHA seeks comment on the following:

Is the partial exemption from regulation which OSHA has allowed for research chemicals in paragraph (f) appropriate?

Are the special enforcement provisions OSHA has developed in paragraph (hh) adequate?

Should the compliance dates mandate by paragraph (ii) be either shortened or lengthened?

Are there measures to assure the communication of updated hazard related information preferable to those proposed in paragraphs (z)-(aa)?

D. Selected References

1. National Occupational Hazards Survey, DHEW (NIOSH) Publication No. 78-114, December, 1977.
2. An Interim Report to the Congress on Occupational Diseases, submitted by the U.S. Department of Labor, December, 1979.
3. OSHA Safety and Health Standards for General Industry, 29 CRR Part 1910, OSHA 2206, revised, November 7, 1978.
4. Toxic Substances Control Act Chemical Substances Inventory, and Supplements, U.S. Environmental Protection Agency.

5. The Occupational Safety and Health Act, Pub. L. 91-596, 91st Congress, S. 2193, December 29, 1970.

6. Report of the Standards Advisory Committee on Hazardous Materials Labeling to the Assistant Secretary of Labor of Occupational Safety and Health, U.S. Department of Labor, submitted June 6, 1975.

7. A Recommended Standard * * * An Identification System for Occupational Hazardous Materials, DHEW (NIOSH) Publication No. 75-126, 1974.

8. American National Standard for the Precautionary Labeling of Hazardous Industrial Chemicals, American National Standards Institute, ANSI Z129.1-1976.

9. H.P. 750—Legislative Document 958, State of Maine.

10. Title 8, Article 112, State of California.

11. Public Act No. 80-257 and 80-130, State of Connecticut.

12. Act 51, Public Acts of 1980, State of Michigan.

13. 7103-D, State of New York.

14. General Occupational Health Regulations 22-015, State of Oregon.

15. Chapter 149, Commonwealth of Massachusetts.

16. Chapter 290-64 WAC, State of Washington.

17. N.J.A.C. 12:130, State of New Jersey.

18. Toxic Substances Control Act, Pub. L. 94-469, October 11, 1976.

19. Environmental Protection Agency, Pesticide Programs, 40 CFR Part 162.

20. Environmental Protection Agency, Pesticide Programs, Registration, Reregistration and Classification Procedures (40 FR 28242, July 3, 1975).

21. Environmental Protection Agency, Registration of Pesticides in the United States Proposed Guidelines (43 FR 29596, July 10, 1978).

22. Department of Transportation, Hazardous Materials Transportation, 49 CFR Part 172.

23. Consumer Product Safety Commission, Federal Hazardous Substance Act Regulations, 16 CFR Part 1500.

24. Food and Drug Administration, Food for Human Consumption, 21 CFR Part 100; Drugs, 21 CFR Part 200; Cosmetics, 21 CFR Part 700.

25. Committee on Government Operations, House of Representatives, Transcript of Hearings Before a Subcommittee on Control of Toxic Substances in the Workplace, May 11, 12, and 18, 1976.

26. Committee on Government Operations, House of Representatives, Thirty-Fourth Report, Chemical Dangers in the Workplace, 1976.

27. Committee on Government Operations, House of Representatives, Tenth Report, Failure to Meet Commitments Made in the Occupational Safety and Health Act, 1977.

28. Transcripts of OSHA Hearings on "Access to Employee Exposure and Medical Records", Docket No. H-112.

29. Fair Packaging and Labeling Act, Pub. L. 84-755, s2, Nov. 3, 1966, 80 Stat. 1296.

30. European Economic Community Labeling Requirements, Directive 67/548/EEC, August 16, 1967, as amended by Directive 79/831/EEC, September 18, 1979; Directive 73/173/EEC, June 4, 1973; Directive 77/728/EEC, November 7, 1977; and Directive 78/631/EEC, June 26, 1978.

31. Bureau of Labor Statistics, Occupational Injuries and Illnesses in the United States by Industry, 1977.

32. Pilot Study for Development of an Occupational Disease Surveillance Method, DHEW-NIOSH 75-162, 1975.

33. Draft I.R.L.G. Guideline for Documentation of Epidemiologic Studies, Interagency Regulatory Liaison Group, November, 1979.

34. Creech and Johnson, *Angiosarcoma of the Liver in the Manufacture of Polyvinyl Chloride*, 16 J. Occ. Med. 150 (1974).

V. Legal Authority

This notice of proposed rulemaking is being published in conformity with the requirements of section 6(b)(2) of the Occupational Safety and Health Act, 29 U.S.C. 655(b)(2), for publishing a proposed rule promulgating an occupational safety and health standard in the Federal Register, and section 4(b) of the Administrative Procedure Act, 5 U.S.C. 553(b) regarding the publication of notices of proposed rulemakings in the Federal Register.

Authority for issuance of this standard is found in sections 6(b) and 8(g)(2) of the Act, 29 U.S.C. 655(b) and 657(g)(2). Section 6(b) governs the issuance of an occupational safety and health standard, which is defined in section 3(8) of the Act, 29 U.S.C. 652(8), as:

[A] standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment.

The proposal contemplates the issuance of a generic standard for the determination and communication of workplace hazards. This will require the adoption and use of one or more practices (e.g. labeling and access to records) which the secretary has reason to believe are reasonably necessary and

appropriate to provide employees with safe and healthful employment and places of employment. The issuance of a generic standard is a necessary and effective means to carry out the purposes of the Act and to set priorities under the Act whenever the Secretary identifies common occupational health or safety problems which warrant common solutions (see the Cancer Policy standard, 45 FR 5002 et seq., and the access to exposure to exposure and medical records standard, 45 FR 35212 et seq.).

In particular, the proposed standard is a generic implementation of sections 6(b)(7) and 6(b)(5) of the Act, 29 U.S.C. 655(b)(7) and (b)(5). Section 6(b)(7) pertinently states that:

Any standard promulgated under this subsection shall prescribe the use of labels or other appropriate forms of warning as are necessary to insure that employees are apprised of all hazards to which they are exposed, relevant symptoms and appropriate emergency treatment, and proper conditions and precautions of safe use or exposure * * *

Section 6(b)(5) authorizes the Secretary, in promulgating standards dealing with toxic materials or harmful physical agents:

* * * to set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life * * *

The philosophy of this proposal is to require the identification and disclosure of a hazard to employees as soon as the scientific literature reliably indicates such a conclusion, even though the evidence or OSHA's priorities may not yet warrant comprehensive regulation of the hazardous chemical. This is consistent with the Supreme Court's statement in *Industrial Union Dep't (IUD) v. American Petroleum Institute (API)*, 100 S.C.T. 2844, at 2872, fn. 66 that Congress had an "information-gathering function" in mind when it enacted section 6(b)(7), and that requirements of this nature may be imposed at lower levels than can currently be set for the regulation of a toxic substance on the basis of a finding of significant risk. This is so because it is necessary to "keep a constant check on the validity of the assumption made in developing the permissible exposure limit, giving it a sound evidentiary basis for decreasing the limit if it was initially set too high," id. at 2872, or, *a fortiori*, not at all.

The Secretary's authority to issue this proposed standard is further supported by the general rulemaking authority

granted in section 8(g)(2) of the Act. This section empowers the Secretary "to prescribe such rules and regulations as he may deem necessary to carry out [his] responsibilities under the Act." The authority thus granted to the Secretary is as broad as the purposes of the Act, which include:

Encouraging employers and employees in their efforts to reduce the number of occupational safety and health hazards at their places of employment, and to stimulate employers and employees to institute new and to perfect existing programs for providing safe and healthful working conditions (29 U.S.C. 651(b)(1)).

Building upon advances already made through employee and employer initiative for providing safe and healthful working conditions (29 U.S.C. 651(b)(4)).

Exploring ways to discover latent diseases, establishing causal connections between diseases and work in environmental conditions * * * (29 U.S.C. 651(b)(6)).

Encouraging joint labor-management efforts to reduce injuries and diseases arising out of employment (29 U.S.C. 651(b)(13)).

OSHA believes that this proposal, when issued in final form, will significantly advance these statutory goals.

In addition, Section 8(c)(1) of the Act, 29 U.S.C. 657(c)(1), authorizes the Secretary to issue regulations requiring employers to, "make, keep and preserve, and make available to the Secretary * * * such records regarding his activities relating to this Act as the Secretary * * * deems necessary or appropriate for the enforcement of this Act or for developing information regarding the causes and prevention of occupational accidents and illnesses."

This proposal directs its major obligations toward those employers who are in the best position to develop information concerning chemical hazards or who are the primary users of chemicals in industry. To this end, "manufacturers" and "industrial users" are limited, by definition, to employers in Division D (Manufacturing), Major Groups 20-39, of the SIC Manual. In issuing standards, the Secretary may, under his section 6(g), 29 U.S.C. 655(g), priority-setting discretion apply the standard only to certain segments of business, thus "[giving] due regard to the urgency of the need for mandatory safety and health standards for particular industries, trades, crafts, occupations, businesses, workplaces or work environments."

The system of hazard identification and communication established by this proposal is also designed to impose the duty of hazard evaluation primarily on the manufacturers and importers who distribute hazardous chemicals in commerce. It would require the

ward related information employees involved in the chemicals but also to the chemicals are to benefit of the employees. This approach is OSHA used in its and which was relevant part by the Court *American Petroleum Institute*, 581 F. 2d 493 (5th Cir. 1978), vacated on other grounds *sub nom. Dep't., AFL-CIO v. Petroleum Institute*, 100 S. ct. The Court stated (*id.* at 510): the responsibility to warn employees of concealed hazards from employers who create the know of the hazard is consistent purpose of the Act and is OSHA's broad authority to prescribe labels.

The Court was also influenced by the upstream employer's own employees were exposed to the same hazards and had to be warned via labels event. The responsibility to warn upstream employees placed on manufacturers by this proposal is not actually different than in benzene. In benzene, their own employees are at least as much exposed to the chemicals which they must evaluate for hazards and provide warning for accordingly. OSHA recognizes, however, that importers may be in a different position than manufacturers since, if they are not themselves manufacturers, they may not have employees exposed in any significant way to the chemicals they ship and may have difficulty getting information concerning the identities and hazards of the chemicals they import from overseas suppliers. Nevertheless, the proposal treats importers like manufacturers because it appears necessary that chemical identification and hazard warnings be developed at the earliest possible point in the chain of distribution after a chemical enters the Customs Territory of the United States to avoid a significant regulatory gap. Cf. *Mourning v. Family Publications Services*, 411 U.S. 356 (1973). OSHA specifically invites comment on how best to regulate hazardous imported chemicals so that employees may be informed of their chemical identity and warned of their hazards.

VI. Regulatory Analysis, Environmental Impact and Regulatory Flexibility Requirements

This proposal has been developed in conformity with pertinent laws, regulations, and executive orders. In particular, pursuant to Executive Order

12044 and the implementing Secretary's Order (44 FR 5370; January 28, 1979) OSHA has developed a Regulatory Analysis that extensively considers the expected benefits and economic impacts of the proposed standard, together with regulatory alternatives considered by the Agency. This document is available to the public from the following address: Docket Officer, Docket No. H-022, Room S-8212, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210; Tel: (202) 523-7894.

The Regulatory Analysis also serves as the Agency's draft Environmental Impact Statement (EIS) and Regulatory Flexibility Analysis. Under the National Environmental Policy Act, 42 U.S.C. 4321 *et seq.*, as interpreted by 40 CFR Part 1500 *et seq.* (Council on Environmental Quality) and 29 CFR Part 11 (Department of Labor), (45 FR 51187 *et seq.*; August 1, 1980) OSHA is required to prepare a draft EIS if it determines that a proposed action will have significant environmental effects. Because OSHA has identified significant, albeit beneficial, effects external to the workplace resulting from this proposed standard, the Regulatory Analysis has accordingly been written so that it may simultaneously function as the draft EIS. The consolidation of documents in this manner is explicitly permitted by 40 CFR 1506.4 and 29 CFR 11.12(d). In addition to assuring that the substantive subject matter required of a draft EIS has been addressed, OSHA has also undertaken to comply with the notice and filing requirements set forth in the NEPA regulations, 40 CFR 1506.6 and 1506.9 and 29 CFR 11.12(d).

In like manner, the Regulatory Analysis also contains an analysis of the proposed standard's impact on small businesses, as required by the Regulatory Flexibility Act of 1980, Pub. L. 96-353. As detailed in the Regulatory Analysis and in the preamble above, OSHA has not only considered the effects on small businesses, but also has taken steps designed to lessen the compliance burden on manufacturers and importers with 250 or fewer employees. The decision at this time to limit the scope of the proposed standard primarily to employers engaged in manufacturing (Division D, SIC Major Groups 20-39)—thereby excluding construction and other non-manufacturing industries from its scope—may also be seen in part as an attempt to minimize the impact of the proposed standard on small businesses. To the extent necessary, OSHA will issue a final EIS and Regulatory Flexibility Analysis at the time of the final standard. It will also make final

determinations regarding the technical and economic feasibility of the standard. To assist it in this task, the Agency specifically invites comments on any issue relating to the benefits, costs and other economic impacts, environmental consequences, and impacts on small business of the proposed standard.

VII. Public Participation

Interested persons are invited to submit written data, views, and arguments on this proposed standard. These comments must be received on or before April 18, 1981, and submitted in quadruplicate to the Docket Officer, Docket H-022, U.S. Department of Labor, Occupational Safety and Health Administration, 200 Constitution Avenue, N.W., Room S-6212, Washington, D.C., 20210; (202) 523-7894. Written submissions must clearly identify the provisions of the proposal which are addressed, and the position taken on each issue.

OSHA is scheduling public hearings in several locations to permit interested persons an opportunity to submit oral testimony concerning the issues raised by the proposed standard, including the economic and environmental impacts. The dates and cities for these hearings are as follows:

Date Hearing Will Begin in City

1. May 26, 1981, Washington, D.C.
2. July 7, 1981, Houston, Texas.
3. July 21, 1981, Chicago, Illinois.
4. August 11, 1981, Philadelphia, Pennsylvania.
5. September 1, 1981, San Francisco, California.

The addresses for the location of the hearing in each city will be announced in the Federal Register at a later date.

Notices of Intention to Appear

All persons wishing to participate in the public hearings must file a notice of intention to appear, in quadruplicate, on or before May 1, 1981, addressed to Mr. Tom Hall, OSHA Division of Consumer Affairs, Docket No. H-022, Room N3635, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210; (202) 523-8024.

The notices of intention to appear must contain the following information:

- (1) The name, address and telephone number of each person to appear;
- (2) The capacity in which the person will appear;
- (3) The approximate amount of time requested for the presentation;
- (4) The specific issues that will be addressed;

(5) A detailed statement of the position that will be taken on each issue addressed; and

(6) Whether the party intends to submit documentary evidence and if so, a brief summary of that evidence.

Filing of Testimony and Evidence Before Hearing

Any party requesting more than 15 minutes for a presentation at the hearing, or submitting documentary evidence, must provide in advance the complete text of the testimony or documentary evidence to be presented. These texts shall be submitted in quadruplicate to the OSHA Division of Consumer Affairs, at the above address, and must be submitted by May 8, 1981.

These submissions will be available for inspection and copying at the OSHA Docket Office, Room S-6212, at the above address.

Each submission received will be reviewed to ascertain if the amount of time requested in the notice of intention to appear is appropriate. In those instances where the information contained in the submission does not justify the amount of time requested, a more appropriate time allocation will be made and the participant will be notified of the change. Any party who has not substantially complied with this requirement may be limited to a 15-minute presentation, and may be requested to return for questioning at a later time.

Conduct of Hearings

The hearings will begin at 9:30 a.m. with resolution of any procedural matters relating to the proceeding. The hearings will be conducted in accordance with 29 CFR Part 1911, allowing full development of the record and permitting all parties to exercise their rights of participation.

The hearing will be presided over by an Administrative Law Judge who will have all the powers necessary or appropriate to conduct a full and fair informal hearing as provided in 29 CFR Part 1911. Following the close of the hearing or of any post hearing comment period, the presiding Administrative Law Judge will certify the record to the Assistant Secretary of Labor for Occupational Safety and Health.

All written and oral submissions, as well as other information gathered by the Agency, will be considered in any action taken. The record of this rulemaking, including written comments and materials submitted in response to this notice and notices of intention to appear at the public hearings, will be available for inspection and copying in the Docket Office, Room S-6212, at the

above address, between the hours of 8:15 a.m. and 4:45 p.m.

VIII. Authority and Signature

This document was prepared under the direction of Eula Bingham, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20210.

(Secs. 6(b), 8(c), and 8(g). Pub. L. 91-596, 84 Stat. 1593, 1599, 1600; 29 U.S.C. 655, 657; 29 CFR Part 1911; Secretary of Labor's Order No. 8-76 (41 FR 25059))

Signed at Washington, D.C. this 13th day of January, 1981.

Eula Bingham,
Assistant Secretary of Labor.

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I. General

(a) Overview.

Paragraphs (a) and (b) of this standard do not themselves impose requirements on employers but are intended to set forth the general purpose of this standard and to summarize (with appropriate cross-references) the major provisions of the standard which implement that purpose.

This standard establishes a system designed to communicate to workers and employers essential information concerning the hazards of workplace chemicals. Chemicals are classified under the standard as either substances (paragraph (gg)(40)) or mixtures (paragraph (gg)(30)). Employers covered by the standard generally fall into four categories: manufacturers (paragraph (c)(1)(i)), importers (paragraph (c)(1)(ii)), suppliers (paragraph (c)(1)(iii)), and industrial users (paragraph (c)(1)(iv)). Manufacturers and industrial users covered by this standard are those whose establishments are covered by Division D (Manufacturing), Major groups 20-39, in the most recent revision of the Standard Industrial Classification Manual; Executive Office of the President-Office of Management and Budget. In addition, other employers (i.e. those which fall under other SIC categories) are required to leave labels on containers they receive unless or until the container is put up for retail sale (paragraph (v)).

This standard requires (1) the evaluation of substances and mixtures to determine whether they are hazardous according to the criteria specified in the standard (paragraph (i)-(1); Appendices A and B) and (2) certain regulatory actions to be taken with respect to those substances and mixtures which are determined to be hazardous. The responsibility for hazard evaluation is placed on the manufacturers or importers of a substance or mixture because they are in the best position to make such an evaluation. The standard identifies 17 different kinds of hazards which must be evaluated (paragraph (gg)(22)). The evaluation procedures of the standard require manufacturers or importers to make use of information available in

own records and to search relevant literature for evidence of those hazards (paragraphs (k)-(l)). Appendices A and B of the standard apply the accepted scientific principles that are to be followed when evaluating the evidence indicating a hazard. The evaluation procedures of the standard, however, do not require manufacturers and importers to perform any tests to determine the hazard of a substance or mixture.

When a substance or mixture is determined by a manufacturer or importer to be hazardous under the standard, the standard requires each manufacturer and industrial user to:

(1) Label every container of every hazardous substance in the workplace with the precise chemical identity of its contents, and with appropriate hazard warnings, (paragraph (q) and Appendix C);

(2) Label every container of a mixture with the precise chemical identities of the constituent chemicals which are or may be hazardous, and with appropriate hazard warnings (paragraph (q) and Appendix C);

(3) Provide employees with any available material safety data sheets concerning the dangers posed by hazardous substances and mixtures in the workplace (paragraph (cc)); and

(4) Update the information provided to employees as new information about hazards becomes available (paragraphs (x)-(aa)).

To provide the information which industrial users need to protect their employees, the standard requires manufacturers and importers to:

(1) Maintain files (i.e. references, studies, reports or other documents used in the hazards evaluation procedure) on all substances and mixtures they manufacture or import (paragraph (m));

(2) Assure that the appropriate chemical identity and hazard warning labels are affixed to containers that are being shipped to industrial users and the suppliers of industrial users (paragraph (o)); and

(3) Provide with the first shipment to an industrial user or supplier of an industrial user one copy of any safety data sheet which the manufacturer or importer has developed concerning the hazards posed by the substance or mixture being shipped (paragraph (o)(6)). The standard, however, does not require safety data sheets to be developed or published if they do not otherwise exist.

To assure that industrial users receive the chemical identification and hazard warning information developed by the manufacturer or importer, the standard

requires suppliers to forward this information which they receive from manufacturers or importers with their shipments of hazardous substances and mixtures to industrial users and to other suppliers of industrial users (paragraph (o)(5)). The standard permits industrial users, for the purposes of complying with their labeling and placarding duties, to rely on the hazard-related information which they receive from manufacturers, importers or suppliers. (paragraph (p)).

The standard requires that material safety data sheets and files containing hazard determination references and documents must be preserved for specified periods of time. (paragraph (bb)). Access to these records is generally provided to employees (including former employees), their designated representatives (including unions with collective bargaining rights in the workplace), OSHA and NIOSH (the National Institute for Occupational Safety and Health, Department of Health and Human Services). (paragraphs (cc) and (dd)). The standard provides for the transfer of these records when an employer subject to its recordkeeping provisions goes out of business (paragraph (ee)). The standard also requires each manufacturer and importer to send to OSHA, after completing a hazard determination on a substance or mixture, either a notice stating that the substance or mixture has not been found to meet the criteria for a hazard or a copy of the appropriate hazard warning for the substance or mixture. This information will be kept in a central repository and made available to other employees on request (paragraph (w)). The compliance dates of the standard have been extended by three months for manufacturers and importers with less than 250 employees so that they may take advantage of the hazard evaluations on file with OSHA (paragraph (ii)).

(b) Purpose.

The system of hazards evaluation and communication established by this standard will, by making information about workplace hazards generally available to workers, their representatives, OSHA and NIOSH, yield direct and indirect improvements in occupational health. Container labels will give workers immediate access to the identities and dangers of the hazardous substances and mixtures with which they work directly. Material safety data sheets will provide workers and their representatives with detailed information about the properties and handling of hazardous substances and mixtures, supplementing the information

on hazard warning labels. Hazard evaluation files will provide the documentation to enable workers and their representatives to make their own hazard determinations and to check the employer's determinations.

II. Scope and application

(c) Employers covered by the standard.

(1) This standard applies to any employer who:

(i) Is engaged in the manufacturing or processing of a substance or mixture for distribution in commerce and whose business is covered by Division D (Manufacturing), Major Groups 20-39, in the most recent revision of the *Standard Industrial Classification Manual*, Executive Office of the President—Office of Management and Budget (hereafter "manufacturer"); or

(ii) Imports a substance or mixture into the Customs Territory of the United States (i.e., the 50 States, Puerto Rico, and the District of Columbia), and is the first person who, knowing the substance or mixture will be imported, controls the identity and total amount of the substance or mixture to be imported (hereafter "importer"); or

(iii) Receives a substance or mixture regulated by this standard and distributes such substance or mixture to an industrial user or another supplier of an industrial user in unaltered form, whether or not in its original container (hereafter "supplier"); or

(iv) Uses a substance or mixture received from a manufacturer, importer, or supplier, and whose business is covered by Division D (Manufacturing), Major Groups 20-39, in the most recent revision of the *Standard Industrial Classification Manual*, Executive Office of the President—Office of Management and Budget (hereafter "industrial user").

(2) This standard applies to employers who are neither manufacturers, importers, suppliers, or industrial users only to the extent set forth in paragraph (v).

(d) Substances covered by the standard.

(1) Any substance covered by this standard must be evaluated in accordance with paragraphs (i)-(1) and Appendices A and B.

(2) This standard applies to any substance which is:

(i) Listed in the Toxic Substances Control Act Chemical Substance Inventory, including UVCBs; or

(ii) A pesticide; or

(iii) A food additive, a prior sanctioned food additive, a color additive, cosmetic or a drug; and includes

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(i) A workplace covered by this standard for personal use by employees; or

(ii) A destination other than a workplace covered by this standard.

(b) An importer who does not know the contemplated use or ultimate destination of a substance must evaluate such substance for hazards.

III. Evaluation and Communication of Hazards—Duties of Manufacturers and Importers

(i) Evaluation of substances and mixtures for hazards.

(1) Each manufacturer and importer of a substance covered by this standard shall determine whether that substance is to be regulated as a hazard in accordance with the requirements of paragraphs (j)-(l) and the procedures set forth in Appendices A and B.

(2) The manufacturer or importer of a mixture shall determine that it poses the hazards of its constituent substances if:

(i) The mixture contains a constituent substance in an amount of at least 0.1% (by weight) which is determined to be a carcinogen, unless the mixture as a whole is determined not to be a carcinogen (Appendices A and B); or

(ii) Any of the constituent substances of the mixture in an amount of at least 1.0% (by weight) meets the definition for one or more Category A or Category B hazards, and the mixture as a whole cannot be evaluated for that Category A or B hazard because of a lack of adequate information about the mixture's effects.

(3) If there is adequate information (Appendix A) to evaluate a mixture for a particular Category A or Category B hazard, the mixture shall be determined to be hazardous if, evaluated as a whole, it meets the definition of such a hazard. In such case, its constituent substances need not be evaluated for the same hazards.

Note.—For purposes of paragraphs (2) and (3), "adequate information" means studies or data which meet the requirements of Appendices A and B.

(4) Where a hazard can be traced to a general chemical structure (i.e., a chemical family), but not to a particular substance, the most specific chemical structure to which the hazard can be traced, and which the mixture contains in an amount of at least 1.0% (by weight), shall be treated for purposes of this standard as a substance.

(j) Categories of hazards.

An importer or manufacturer shall determine hazardous properties of substances and mixtures under two distinct sets of criteria and procedures. To reflect this fact, hazardous properties

have been grouped in two categories, "Category A" (physical hazards) and "Category B" (health hazards) according to the hazard determination criteria and procedures by which they are governed. The hazards in each category are set out under the definition of "hazardous," under paragraph (g)(22).

(k) Determination of Category A hazards.

A Category A hazard exists if:

(1) The substance or mixture possesses the physical or chemical properties specified in the definition for any Category A hazard as determined by the procedure set out in Appendix A; and

(2) The substance or mixture is present in the workplace under normal or emergency working conditions in the physical state and chemical form in which its hazardous properties were ascertained.

(l) Determination of Category B hazards.

A Category B hazard exists if:

(1) A substance meets the definition for any listed category B hazard as demonstrated by the procedures set out in Appendices A and B; and

(2) The substance or mixture is present in the workplace under normal or emergency working conditions in the chemical form in which its hazardous properties were ascertained.

(m) Maintenance of hazard evaluation files.

Each importer or manufacturer must maintain and make available, for examination and copying (see paragraph (dd)), a separate hazard evaluation file for each substance and mixture in the workplace. Each file shall contain all publicly unavailable documents, and a list of all publicly available documents and their sources, submitted to or in the possession of the importer or manufacturer concerning the substance or mixture relevant to the hazard determination process.

(n) Deletion from hazard evaluation files of trade secret information.

(1) An importer or manufacturer may delete from any publicly unavailable document produced for an employee, former employee, or certified or recognized collective bargaining agent, trade secret information which discloses manufacturing processes, or which discloses the percentage of a substance in a mixture.

(2) An importer or manufacturer may also delete from any publicly unavailable document produced for an employee, former employee, designated representative, or collective bargaining agent, trade secret information which discloses the chemical name of CAS number of a substance or a mixture:

(i) Where the importer or manufacturer has determined that the substance or mixture to which such document pertains is not hazardous; or

(ii) Where the importer or manufacturer has not yet determined whether such substance or mixture is hazardous; or

(iii) Where the substance or mixture is used solely in research as described in paragraph (f).

(3) Information which an importer or manufacturer is required to disclose to any agency of the federal government, or to any state or subdivision of a state, and which is available to competitors or the public without compensation to the provider of the information, shall not be considered "publicly unavailable" information entitled to trade secret status.

(o) *Information to accompany shipments.*

(1) No shipment of a hazardous substance may be sent by a manufacturer or importer to an industrial user or supplier, unless each container is labeled with the following information:

(i) The common name of the substance;

(ii) The CAS number of the substance; and

(iii) The appropriate hazard warning label prescribed by Appendix C.

(2) No shipment of a regulated mixture may be sent by a manufacturer or importer to an industrial user or supplier, unless each container is labeled with the following information:

(i) The common name of the mixture;

(ii) The CAS numbers and common names of all hazardous constituent substances in a mixture listed in order of relative concentration, by CAS number, with the substance of greatest concentration being listed first; and

(iii) The appropriate hazard warning label prescribed by Appendix C.

(3) The chemical names of substances and constituent substances of mixtures may either be placed on labels prepared for shipment, or may be forwarded, with appropriate cross references to common names and CAS numbers, in a separate listing accompanying the shipment.

(4) No shipment of a substance or mixture determined not to be hazardous may be sent by a manufacturer or importer to an industrial user or supplier without a written statement that the substance or mixture has been evaluated in compliance with this standard and found not to meet the criteria for a hazard as defined by this standard. Any industrial user or supplier who receives such a statement must forward it with any shipment of such

substance or mixture to any other industrial user or supplier.

(5) A supplier who receives a shipment from an importer or manufacturer accompanied by the information described in this paragraph shall carry forward such information in any further shipment using either the labeling or separate listing format.

(6) Each importer, manufacturer, or supplier shall supply with the first shipment of a hazardous substance or a hazardous mixture to any workplace of any industrial user or supplier, one copy of any available material safety data sheet concerning such substance or mixture.

(7) Each printing of a material safety data sheet must reflect the most current pertinent information in possession of the importer or manufacturer who supplies it.

(8) An importer or manufacturer who does not know the contemplated use or ultimate destination of a shipment shall forward information as required by this paragraph with the shipment.

(9) A shipment of a hazardous substance or mixture by an importer or manufacturer shall not be subject to the labeling requirements of this paragraph if another OSHA standard has specific labeling requirements affecting the substance or mixture different from those of this paragraph. In such cases, an importer or manufacturer shall label in accordance with the requirements of the specific standard and shall assure that the label remains affixed to the container when sent to an industrial user or supplier.

(10) A hazardous substance or mixture which has been finally processed to a solid state, whether originally a solid, liquid or gas, and is inert and not susceptible to decomposition in any workplace, shall be subject only to the requirements of paragraph (o)(4).

IV. Workplace Requirements

(p) *Responsibility to determine hazards—industrial users and suppliers.*

An industrial user or supplier receiving a shipment may rely upon the determination by a manufacturer or importer that a hazard does or does not exist as required to be forwarded by paragraph (o) with shipments of substances and mixtures. However, an industrial user who has actual knowledge of hazards posed by a substance or mixture generally, or as used in the workplace, which has not been communicated to the industrial user by the manufacturer or importer, must convey the information regarding such hazards, as required by this standard, to his or her employees.

(q) *Workplace labels for hazardous substances and mixtures.*

(1) Except as provided by paragraph (u), each manufacturer and industrial user shall ensure that each container of a hazardous substance in the workplace is labeled with the common name and CAS number of the substance within.

(2) Each manufacturer and industrial user shall ensure that each container of a hazardous mixture in the workplace is labeled with:

(a) The common name of the mixture.

(b) The common name(s) and CAS number(s) of the mixture's hazardous constituent substances, listing CAS number(s) first. Constituent hazardous substances shall be listed on the label in order of relative concentration with the substance of highest concentration being listed first.

(3) Each manufacturer and industrial user shall ensure that each container of a hazardous substance or mixture in the workplace is labeled with the appropriate hazard warning label indicated in Appendix C.

(r) *Workplace labels or placards—piping systems.*

(1) The hazardous contents of a piping system shall be identified by labels or placards. Labels or placards shall be placed at reasonable intervals along the piping system in places accessible to employee view. Labels or placards shall show the common name, the CAS number, and the hazard warning for each hazardous substance and mixture flowing through the piping system.

(2) Whenever an employee is assigned to do maintenance or repair work on a pipe, the employee must be notified of at least the common name and the hazard warnings pertinent to the substance or mixture in the pipe.

(s) *Hazard warning labels of other agencies.*

(1) Each manufacturer and industrial user shall ensure that hazard warning labels affixed to containers of substances or mixtures to comply with the regulations of other Federal agencies are not removed or obscured after entering the workplace. Such labels need not be transferred to other workplace containers into which a substance or mixture is subsequently placed.

(2) In addition to the common names and CAS numbers required by paragraph (q), a manufacturer or industrial user may use labels affixed in accordance with requirements of the Department of Transportation, 49 CFR Part 172, and the Environmental Protection Agency, 40 CFR Part 162, in lieu of the hazard warnings required by paragraph (q) and indicated by Appendix C of the standard.

(t) Label and placard display requirements.

(1) A label must be displayed on, or securely affixed to, the surface of the container. For the purposes of this section, "securely affixed" means that a label can reasonably be expected to remain affixed and legible during foreseeable conditions and the period of use. If a hazardous substance or mixture is packaged in a container that has a separate inner liner, the hazard warning label must be securely affixed to the outer surface of the container and not to the inner liner.

(2) A label or placard must be prominently displayed. Prominent display shall be achieved by the use of distinct typography and colors that contrast sharply with the background, and in the use of suitable size, design, and placement. In addition, any label which is affixed to comply with this standard shall contain a statement to that effect.

(3) A label or placard must be clearly legible to a person with normal vision. A label or placard must not be obscured by any other marking on the container (such as advertising) that could substantially reduce its legibility.

(4) All required label or placard text must be printed in English, and may be printed in languages other than English as well.

(5) A label or placard may include additional hazard warning information not required by this section, provided that the additional information does not contradict or detract from the required information. Terms such as "safe," "non-toxic," or "harmless" shall not appear on the label or placard.

(6) Chemical identification and hazard warning components may be included on a single label or appear on separate labels.

(7) A manufacturer or industrial user who refills a labeled container of a hazardous substance or mixture must remove or mask the hazard warning label before refilling the container with another substance or mixture.

(8) A manufacturer or industrial user need not change labels or placards to reflect every stage of a continuous reaction or every change in the contents of a container or pipe, provided the manufacturer or industrial user adopts any alternative system or format which:

- (i) Utilizes labels and placards;
- (ii) Accurately conveys the same information as would changing individual labels or placards contemporaneously with changing the contents of the container or pipe;
- (iii) Is immediately accessible to employees nearby; and

(iv) Assures that all employees assigned to work on pipes or their attachments, labeled or placarded under this paragraph, are informed at all times of the chemical identity and hazard warnings appropriate to the contents of such pipes or containers.

(u) Exceptions from workplace labeling and placarding requirements of this section.

A manufacturer or industrial user need not label workplace containers as required by paragraph (q) or use placards as provided for in paragraph (r) if:

(1) The container is five gallons (19.0 liters) or less in volume, is used to transfer hazardous substances or hazardous mixtures from labeled containers, and is intended only for use in the work area where the transfer occurs; or

(2) Another OSHA standard has specific labeling or placarding requirements affecting a substance or mixture which are different from those of paragraph (q), in which case the manufacturer or industrial user shall label or placard in accordance with the requirements of the specific standard; or

(3) The hazardous substance or mixture, whether originally a solid, liquid or gas, has finally been processed to a solid state and is inert and not susceptible to decomposition in the workplace.

(v) Labeling duties of other employers.

Each employer who is not a manufacturer, importer, industrial user or supplier, and who receives a container labeled in compliance with this section, shall not remove or obscure the label unless and until the container is actually put up for retail sale.

(w) Label reference service.

(1) Upon completion of the hazard determination for a substance a manufacturer or importer of such substance shall forward to the Assistant Secretary within 60 days of such determination either:

(i) Notice that the chemical substance has been evaluated and determined not to meet the criteria for a hazard as defined by this standard; or

(ii) Notice that the substance is hazardous.

(2) Each notice shall include the common name, the chemical name, and the CAS number of the substance in question.

(3) The notice for a hazardous substance must also include all hazard warning information required by this standard to appear upon the container label.

(4) The Assistant Secretary will maintain a registry of the information

required to be reported under this paragraph.

(5) Any manufacturer or importer may have access to the notices submitted for any substance appearing in the registry. The manufacturer or importer requesting this information must identify a substance by either its chemical name or its CAS number. OSHA will not release any information concerning the common name or trade name of any substance, or the identity of any manufacturer or importer of a substance.

(6) Information obtained from the registry may be relied upon to comply with the hazard determination and hazard warning requirements of this standard. Users of the registry are, however, under a continuing obligation to ensure that hazard determinations and hazard warnings are up to date.

(7) OSHA will charge users of the registry a reasonable fee reflecting the cost to OSHA of providing the requested information.

V. Updating Hazard Information and Hazard Determinations**(x) Duty to update—importers and manufacturers.**

(1) Whenever an importer or manufacturer acquires private or public information:

(a) Concerning new hazards a hazardous substance or mixture has been found to pose;

(b) Concerning additional information about the hazards such substance or mixture has been found to pose; or

(c) Indicating that a substance or mixture previously determined to pose a hazard does not pose such hazard, the hazard determination for such substance or mixture and the information pertinent to it shall be updated accordingly.

(2) The procedures governing the determination of hazards under paragraphs (i)-(1) and Appendices A and B shall govern the determination of new hazards under this paragraph.

(y) Duty to update—industrial users.

Whenever an industrial user has actual knowledge, contrary to the information previously received with the shipment of a substance or mixture, that the substance or mixture is hazardous, or poses hazards additional to those of which he or she was informed, the industrial user shall revise the hazard determination for use in the workplace. An industrial user need not forward the revised determination, or the information underlying it, however, unless the information underlying the revised determination was actually generated by the industrial user. Likewise, where an industrial user discovers new information about the hazards of a currently hazardous

substance or mixture, such information need to be forwarded only if actually generated by the industrial user.

(z) Communication of updated hazard determinations and information.

(1) Updated hazard determinations and hazard information generated or received by an importer or manufacturer shall be distributed promptly as follows:

(i) To each industrial user, or supplier, to whom the importer or manufacturer has supplied the substance or mixture to which the updated determination or information refers within the lesser of:

(A) The period from the effective date of this standard (see paragraph (kk)) to the date the updated determination was made or the updated information was acquired; or

(B) The 24 month period immediately preceding the date the updated determination was made or acquired.

(2) Updated determinations and information generated by an industrial user shall be distributed promptly to the importer, manufacturer, or supplier who last supplied the substance or mixture to the industrial user.

(3) A supplier who receives an updated determination or updated information shall distribute it to the last manufacturer or importer who supplied the substance or mixture to the supplier. In addition such determinations and information shall be distributed promptly to each industrial user and supplier of an industrial user to whom the supplier has supplied the substance or mixture to which the updated determination or information refers within the lesser of:

(i) The period from the effective date of this section (see paragraph (kk)) to the date the updated determination was made or the updated information was acquired; or

(ii) The 24 month period immediately preceding the date the updated determination was made or the updated information was acquired.

(aa) Duties upon receipt of updated information.

(1) Each manufacturer and industrial user shall promptly make updated hazard information available with all relevant material safety data sheets.

(2) Each importer, manufacturer, industrial user, or supplier shall promptly revise relevant labels and information to accompany shipments to reflect accurately updated hazard determinations.

VI. Recordkeeping and Access Requirements.

(bb) Records preservation.

(1) Each manufacturer and industrial user shall preserve a copy of a material safety data sheet (if any) until it is

replaced by a more recent copy or until the hazardous substance or mixture to which it pertains is no longer present in the workplace.

(2) Each importer and manufacturer shall preserve the hazard evaluation files required by paragraph (m) for three years.

(3) Each manufacturer and industrial user shall preserve the statement that a substance or mixture has been evaluated and determined not to meet the criteria for a hazard as defined by this standard unless and until the substance or mixture to which it applies is determined to be hazardous or the substance or mixture is no longer present in the workplace.

(cc) Access to records.

Within 48 hours of a request for any hazardous substance or mixture in a work area, each manufacturer or industrial user shall supply a copy of any available material safety data sheet, and the chemical name of any hazardous substance or constituent hazardous substance of a mixture, appropriately cross-referenced to the common name and CAS number, in writing to:

(1) Any employee assigned to, formerly assigned to, or about to be assigned to that work area.

(2) Any former employee who was assigned to that work area.

(3) The designated representative of any such employee or former employee.

(4) The recognized or certified bargaining representative for any employee in the workplace.

(5) The Assistant Secretary.

(6) The Director.

(dd) Access to hazard evaluation files.

(1) Within 7 calendar days of a request, each importer or manufacturer shall make available for examination and copying all publicly unavailable reports, studies, or other documents used, or being used, to assess whether a substance or mixture is hazardous by this standard, or to develop material safety data sheets or hazard warnings. Such materials shall be made available to the same persons specified in paragraph (cc).

(2) Where reports, studies, or other documents used, or being used, by the importer or manufacturer for such purposes are publicly available, the importer or manufacturer may, within the same time limits, provide a list of each document source, for examination and copying, instead of the reports, studies, or other documents themselves.

(ee) Transfer of records.

(1) Whenever an importer, manufacturer or industrial user ceases to do business, he or she shall transfer all records subject to this standard to

his or her successor. The successor shall receive and maintain these records.

(2) Whenever an importer, manufacturer or industrial user ceases to do business and there is no successor to receive and maintain the records subject to this standard, the importer, manufacturer, or industrial user shall notify present or former affected employees who leave the employer's employment after this standard becomes effective of their rights of access to records. Notification shall be given at least three (3) months prior to disposal of such records. Former employees shall be considered notified if written notification has been sent to their last known address with a request to forward such notification.

(3) Whenever an importer or manufacturer ceases to do business and there is no successor to receive and maintain records, or whenever an importer or manufacturer intends to dispose of any hazard evaluation files, the importer or manufacturer shall:

(i) Notify the Director in writing of the impending disposal of records at least three (3) months prior to the disposal of the records. Upon request by the Director, the importer or manufacturer shall transfer such records to NIOSH; or

(ii) Transfer the records to the Director if so required by a specific occupational safety and health standard.

(ff) Duty of a manufacturer or industrial user to inform employee of right of access.

A manufacturer or industrial user shall inform his or her employees of their rights of access to information under the standard. A manufacturer or industrial user may comply with this requirement using any reasonable format, except that:

(1) The information on access required by this paragraph shall be permanently displayed in an area readily observable to employees in each work area, and

(2) The display format shall contain the words "Worker's Right to Know" in conspicuous lettering.

VII. Definitions.

(gg) Definitions.

(1) The following terms shall have the meaning contained in the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 321 *et seq.*, and the regulations issued under that Act: "food," "cosmetic," "drug," "food additive," "prior sanctioned food additive," "food ingredient generally recognized as safe," and "color additive."

(2) "Access" means the right and opportunity to examine and copy.

(3) "Assistant Secretary" means the Assistant Secretary of Labor for

Occupational Safety and Health, U.S. Department of Labor, or designee.

(4) "By-product" means a substance or mixture produced without separate commercial intent during the manufacture or processing of another substance(s) or mixture(s). A "by-product" is covered by this rule whether or not it is volatile.

(5) "Carcinogen" means a substance or mixture which meets the definition of a Potential Occupational Carcinogen as specified in 29 CFR 1990.103 and qualified in 29 CFR 1990.143-144, (45 Fed. Reg. 5282, *et seq.*, January 22, 1980) or is identified in a previous Occupational Safety and Health Administration regulation as a carcinogen (29 C.F.R. Part 1910, Subpart Z).

(6) "CAS number" means the unique identification number assigned by the Chemical Abstracts Service to substances.

(7) "Chemical identity" means the "CAS number" or the "chemical name" of a substance.

(8) "Chemical name" is the scientific designation of a substance in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry (IUPAC) or the Chemical Abstracts Service (CAS) rules of nomenclature.

(9) "Combustible liquid" means any liquid having a flash point at or above 100°F (37.8°C) but below 200°F (93.3°C), except that this term does not include any liquid mixture having one or more components with a flash point at or above 200°F (93.3°C) which together make up 99 percent or more of the total volume. (For test method, see definition of "flash point").

(10) "Common name" means any designation or identification such as code name, code number, trade name, brand name or generic name used by an industrial user to identify a substance or mixture other than by its chemical name.

(11) "Compressed gas" means:

(i) A gas or mixture of gases having in a container an absolute pressure exceeding 40 pounds per square inch at 70°F (21.1°C); or

(ii) A gas or mixture of gases having in a container an absolute pressure exceeding 104 pounds per square inch at 130°F (54.4°C), regardless of the pressure at 70°F (21.1°C).

(iii) A flammable liquid having a vapor pressure exceeding 40 pounds per square inch absolute pressure at 100°F (37.8°C), as determined by the American Standard Method of Test for Vapor Pressure of Petroleum Products (Reid Method), Z11:44-1973 (ASTM D 323-72).

(iv) The contents of a self-pressurized container.

(12) "Container" means any bag, barrel, bottle, box, can, cylinder, drum, stationary storage tank, pipe, pump, reaction vessel, stack, oven or the like that contains a substance or mixture and whose inner surface is in direct contact with the substance or mixture. "Container" does not include a container with total contents of less than 500 milliliters (1.057 pints) in volume or less than 500 grams (1.102 pounds) in weight.

(13) "Corrosive material" means a substance or mixture which causes visible destruction of, or irreversible alterations in, living tissue by chemical action at the site of contact. A material is considered corrosive if, when tested on the intact skin of the albino rabbit by the method described by the U.S. Department of Transportation in Appendix A to 49 CFR Part 173 (Oct. 1, 1979), it destroys or changes irreversibly the structure of the tissue at the site of contact following an exposure period of no more than four hours.

(14) "Designated representative" means any individual or organization to whom an employee or former employee gives written authorization to exercise such employee's rights under this standard.

(15) "Director" means the Director, National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designee.

(16) "Emergency" means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment which may or does result in an uncontrolled release of a hazardous substance or hazardous mixture into the workplace.

(17) "Employer" means one or more individuals, partnerships, associations, corporations, business trusts, legal representatives, or any organized group of persons engaged in a business affecting commerce who have employees. The term person does not include the United States or any state or political subdivision of a state.

(18) "Explosive material" means a substance or mixture that causes a sudden, almost instantaneous release of pressure, gas, and heat when subjected to sudden shock, pressure, or high temperature.

(19) "Extremely flammable liquid" means a liquid having a flash point at or below 20°F (-6.7°C) (For test method see definition of "Flash point")

(20) "Flammable" material means a substance or mixture that falls into one of the following categories:

(i) "Flammable aerosol." A substance or mixture dispensed from its container as a mist, spray, or foam by a propellant under pressure which, when tested by the method described in 16 CFR 1500.45 (Jan. 1, 1979), projects a flame longer than 18 inches when the valve is fully open or a flashback (a flame extending back to the valve) at any valve opening;

(ii) "Flammable gas." A gas which at atmospheric temperature and pressure, forms a flammable mixture with air when present at a concentration of 13 percent or less by volume, or the flammable range with air is wider than 12 percent regardless of the lower limit;

(iii) "Flammable liquid." A liquid that has a flash point above 20°F (-6.7°C) but below 100°F (37.8°C), except that this term does not include any liquid mixture having one or more components with a flash point at or above 100°F (37.8°C) which together make up 99 percent or more of its total volume (for test method, see definition of "Flash point");

(iv) "Flammable solid." A solid, other than an explosive that can cause fire through friction, absorption of moisture, spontaneous chemical change, or retained heat from manufacturing or processing, or that can be readily ignited and, when ignited, continues to burn vigorously and persistently after removal of the source of ignition. A material is considered a flammable solid if, when tested by the method described in 16 CFR 1500.44 (Jan. 1, 1979), it ignites and burns with a self-sustained flame at a rate greater than one-tenth of an inch per second along its major axis.

(21) "Flash point" means the minimum temperature at which a liquid gives off a vapor in sufficient concentration to ignite when tested as follows:

(i) Tagliabue Closed Tester (See American National Standard Method of Test for Flash Point by Tag Closed Tester, Z11.24-1979 (ASTM D 56-79))—for liquids with a viscosity of less than 45 Saybolt Universal Seconds (SUS) at 100°F (37.8°C), that do not contain suspended solids and do not have a tendency to form a surface film under test; or

(ii) Pensky-Martens Closed Tester (see American National Standard Method of Test for Flash Point by Pensky-Martens Closed Tester, Z11.7-1979 (ASTM D 93-79))—for liquids with a viscosity equal to or greater than 45 SUS at 100°F (37.8°C), or that contain suspended solids, or that have a tendency to form a surface film under test; or

(iii) Setaflash Closed Tester (see American National Standard Method of Test for Flash Point by Setaflash Closed Tester (ASTM D 3278-78)).

Note.—For mixtures, if the result of any test method described in paragraphs (i)–(iii) is above 100°F (37.8°C), evaporate a fresh sample to 90 percent of the original volume and retest. The lower of the two values shall be taken as the flash point.

(22) "Hazardous" substance or mixture means a substance or mixture which meets the definition for one or more of the terms in the two following groups of hazards:

Category A Hazards

- (i) A corrosive material;
- (ii) An explosive material;
- (iii) An extremely flammable liquid;
- (iv) A flammable material;
- (v) A combustible liquid;
- (vi) A pyrophoric material;
- (vii) A strong oxidizer;
- (viii) A reactive material;
- (ix) A compressed gas;

Category B Hazards

- (x) A highly toxic material;
- (xi) A toxic material;
- (xii) An irritant;
- (xiii) A sensitizer;
- (xiv) A carcinogen;
- (xv) A reproductive toxin;
- (xvi) A material that has acutely endangered the life of a worker of either sex, whether normal or medically disabled, or has caused death from exposure via the respiratory tract (excluding asphyxiation), skin or mouth except that substances or mixtures shall not be placed in this category if available data permit their classification as "highly toxic" or "toxic"; or

(xvii) A material that causes the immediate or delayed onset of other acute, subacute or chronic adverse health effects in humans of either sex, normal or medically disabled, or experimental or domestic animals, if animal models of these human health effects are available.

Note.—Category B hazard (xvii) includes the immediate or delayed onset of acute, subacute or chronic diminution in mental alertness or behavior alterations in humans of either sex, normal or medically disabled, or in experimental or domestic mammals if animal models of these human health effects are available.

(23) "Highly Toxic material" means a substance or mixture that kills within 14 days:

(i) At least half of a group of 10 or more albino rats weighing between 200 and 300 grams each, when administered orally at a single dose of 50 milligrams or less per kilogram of body weight (LD50); or

(ii) At least half of a group of 10 or more albino rabbits weighing between 2 and 3 kilograms each, tested at a dosage of 200 milligrams or less per kilogram of

body weight, when administered by continuous contact with the bare skin for 24 hours (LD50); or

(iii) At least half of a group of 10 or more albino rats weighing between 200 and 300 grams each, tested at a concentration in air of 200 parts per million or less by volume of gas or vapor, or 2 milligrams or less per liter of mist, fume, or dust when administered by continuous inhalation at a steady concentration for one hour or for four hours when there is difficulty maintaining a steady concentration (LC50).

(24) "Impurity" means a substance which is unintentionally present with another substance or mixture.

(25) "Intermediate" means any substance which is present during the manufacture of other substances or mixtures and which either (1) is consumed in whole or in part in the course of manufacturing the other substances or mixtures or (2) is intentionally present for the purpose of altering the rate of such chemical reaction(s) (this latter category includes "catalysts").

(26) "Irritant" means a substance or mixture, not a corrosive, which on immediate, prolonged or repeated contact with living human or mammalian tissue induces the immediate or delayed onset of an acute, subacute or chronic local inflammatory response in the skin, eyes, or mucous membranes by chemical action. A substance or mixture is considered a skin irritant if it receives a score of five or more when tested by the method described in 16 CFR 1500.41 (Jan. 1, 1979). A substance or mixture is considered an eye irritant if a positive result is obtained when tested by the method described in 16 CFR 1500.42 (Jan. 1, 1979).

(27) "Label" means written, printed, or graphic matter displayed on or affixed to the containers of a substance or mixture.

(28) "Labeled container" means a container bearing hazard warning and content labels in accordance with the requirements of the section.

(29) "Material safety data sheet" means any safety data sheet or technical bulletin which contains information regarding the physical, chemical, and hazardous properties of a substance or mixture, e.g., OSHA Form 20.

(30) "Mixture" means any combination of two or more substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that such term does include any combination which occurs, in whole or

in part, as a result of a reaction if none of the substances comprising the combination is a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the substances comprising the combination were combined.

(31) "Other adverse health effects" means diseases, signs, or symptoms which (1) are caused wholly, or in part, by occupational exposures to a hazardous material; (2) occur either immediately or after a latency period which may extend into the retirement period; and (3) for which a reasonably prudent employee would seek medical treatment or a job transfer in order to mitigate or resolve the "other adverse health effect," or (4) which causes loss of consciousness or vision, restriction of worker motion, or has been associated with a reduction in working-life expectancy or total life expectancy. Reductions in working-life or total life expectancy shall be based, directly, upon standard life table methodologies or, indirectly, upon relative or attributable risk methodologies or proportional mortality studies.

(32) "Pesticide" shall have the meaning contained in the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*) and the regulations under that Act.

(33) "Pipes" means any conduits for the transport of gases, liquids, semi-liquids, or fine particulate dust.

(34) "Piping system" means pipes of any type, including fittings, valves, and pipe coverings.

(35) "Pyrophoric material" means a substance or mixture that will ignite spontaneously in dry or moist air at or below 130°F (54.4°C).

(36) "Reactive material" means a substance or mixture that is able to undergo a violent, self-accelerating exothermic chemical reaction with common materials or by itself and includes a substance or mixture that falls within any of the following categories:

(i) "Organic peroxide." An organic compound that contains the bivalent —O—O— structure and which may be considered a structural derivative of hydrogen peroxide, in which one or both of the hydrogen atoms has been replaced by an organic radical.

(ii) "Pressure-generating material." A substance or mixture which may spontaneously polymerize, with an increase in pressure, unless protected by the addition of an inhibitor, or by refrigeration or other thermal control; or which may decompose to release gas in its container.

(iii) "Water-reactive material." A substance or mixture that reacts with water to release heat or a gas which is hazardous.

(37) "Reproductive toxin" means a substance or mixture which causes fetal wastage or undergrowth, malformation, growth retardation, or functional disorders in the products of mammalian conception, or prematurity or diminished fertility in mammals. For the purposes of regulation, it is immaterial whether a specific locus of action has been identified, assignment to this category being based upon the enumerated end-results.

(38) "Sensitizer" means a substance or mixture that causes humans of either sex, normal or medically disabled, or other mammals to develop either a hypersensitive allergic reaction involving normal tissue upon reapplication of the substance or mixture, or a photodynamic reaction. The hypersensitive reaction may be of the anaphylactic, immediate, delayed or fixed type, and may be of acute, subacute or chronic duration.

(39) "Strong oxidizer" means a substance or mixture that initiates or promotes combustion in other materials, thereby causing fire either of itself or through the release of oxygen or other gases.

(40) "Substance" means any organic or inorganic entity of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction, or occurring in nature, and any chemical element or uncombined radical, except mixtures. For purposes of this section, a "UVCB" shall be treated as a chemical substance.

(41) "Toxic material" means a substance or mixture that kills within 14 days:

(a) At least half of a group of 10 or more albino rats weighing between 200 and 300 grams each, when administered orally at a single dose or more than 50 milligrams but not more than 500 milligrams per kilogram or body weight (LD 50); or

(b) At least half of a group of 10 or more albino rabbits weighing between 2 and 3 kilograms each, tested at a dosage of more than 200 milligrams but not more than 1,000 milligrams per kilogram of body weight, when administered by continuous contact with the bare skin for 24 hours (LD 50); or

(c) At least half of a group of 10 or more albino rats weighing between 200 and 300 grams each tested at a concentration in air of more than 200 parts per million but not more than 2,000 parts per million by volume of gas or

vapor, or more than 2 milligrams but not more than 20 milligrams per liter of mist, fume, or dust when administered by continuous inhalation at a steady concentration for one hour or for four hours when there is difficulty maintaining a steady concentration (LC 50).

(42) "UVCB" means a substance or mixture listed in the Toxic Substances Control Act Inventory which is of unknown or variable composition, a complex reaction product or biological material and which has been assigned a CAS number.

(43) "Work area" means a room or defined space in a room or open area where substances or mixtures are manufactured, handled, used, reacted, processed, packaged or repackaged, or transported and where employees are present. For the purposes of this section, each importer, manufacturer, industrial user or supplier shall designate a work area for each employee if no such designation now exists.

(44) "Workplace" means an establishment at one geographical location containing one or more work areas.

VIII. Miscellaneous

(hh) Enforcement.

To the extent and in the manner allowed by law, and for the purpose of determining compliance with this section, employees of OSHA, designated by OSHA, may enter the premises of any importer, manufacturer, industrial user, or supplier to take or require samples of the contents of any container. Pursuant to inspections to determine compliance with this section, the importer, manufacturer, industrial user, or supplier, whose premises are being inspected shall supply to any investigating OSHA employee, upon request, copies of any existing inventories of the substances and mixtures on the premises. These enforcement powers are in addition to OSHA's other enforcement powers which are not specified in this section.

(ii) Compliance dates.

(1)(i) Each manufacturer or importer of a substance or mixture who has two hundred and fifty or more employees shall comply with the provisions of this section as they apply to such substance or mixture within the following time frame:

(A) Regarding a substance, within one year of the effective date of this standard;

(B) Regarding a mixture, within two years of the effective date of this standard.

(ii) Each manufacturer or importer of a substance or mixture who has fewer

than two hundred and fifty employees shall comply with the provisions of this section as they apply to such substance or mixture within the following time frame:

(A) Regarding a substance, within fifteen months of the effective date of this standard;

(B) Regarding a mixture, within twenty-seven months of the effective date of this standard.

(2) Each industrial user and supplier shall comply with the provisions of this section within the following time frame:

(i) Regarding a substance, within two years of the effective date of this standard;

(ii) Regarding a mixture, within three years of the effective date of this standard.

(jj) *Appendices.* The Appendices following this standard are mandatory unless otherwise stated.

(kk) *Effective dates.*

Appendix A—Hazard Determination Procedures

General

(1) A manufacturer or importer must evaluate each substance and mixture specified by paragraphs (d) and (e) of the standard for each of the Category A and Category B hazards listed in paragraph (g)(22) of the standard. Appendix A describes the materials a manufacturer or importer must review, and the evaluative procedures a manufacturer or importer must follow, to determine whether a substance or mixture poses a particular Category A hazard. Appendix A also describes the materials a manufacturer or importer must review in considering whether a substance or mixture poses a particular Category B hazard. Generally, however, materials must be evaluated under the procedures and criteria of Appendix B to determine whether a particular Category B hazard exists.

(2) Unless a manufacturer or importer has hazard data or studies concerning a mixture as a whole and meeting the evaluative criteria of these Appendices, a mixture shall be deemed to pose the hazards of its hazardous constituent substances. For any particular hazard, available data and studies concerning a mixture as a whole meeting these criteria shall take precedence over conflicting data and studies concerning the constituent substances of the mixture.

(3) Hazard determinations may be undertaken individually or jointly by any group of manufacturers and importers.

(b) *Category A Hazard determinations.*

(1) To determine whether a substance or mixture poses a particular Category A hazard, a manufacturer or importer shall utilize the following materials:

(i) Any relevant data or statements contained in the National Library of Medicine's Toxicology Data Bank (TDB) file for a substance, or if there is no relevant information in the TDB, then any relevant information contained in a representative selection of standard reference works and documents published by the National Institute for Occupational Safety and Health.

(A) Standard reference works are textbooks and handbooks listed in the most recent compilation of "Sources Used to Prepare Toxicology Data Bank (TDB) Records" developed by the expert National Institutes of Health scientific peer review group responsible for evaluating information on TDB substances. A selection of standard reference works shall be considered representative if the selected references reflect all applicable techniques for measuring the Category A hazard being evaluated. Where more than one edition of a textbook or handbook is listed, the latest edition which discusses the hazard shall be used.

(B) Where a substance is not listed in TDB, the following NIOSH documents shall be reviewed: Criteria Documents; Special Hazard Reviews; Occupational Hazard Assessments; or Current Intelligence Bulletins.

For further information, contact: Publications Dissemination, DTS, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

(ii) The manufacturer may also use any other relevant data in evaluating a substance or mixture for a Category A hazard.

(2) In the event that the data or statements identified indicate inconsistent conclusions, e.g., categorization as both an extremely flammable and flammable liquid, the manufacturer or importer shall classify a substance or mixture in the greatest hazard category. Where the inconsistency involves the presence or absence of a hazard the manufacturer or importer shall classify the substance or mixture as a hazard.

(3) In evaluating statements or data, the manufacturer shall exercise sound scientific judgment. Statements or data indicating a hazard may be disregarded if the physical measurements on which they are based are shown to be incorrect.

(c) Category B Hazard Determinations.

(1) *Materials To Be Reviewed.* To determine whether a substance or

mixture poses a particular Category B hazard, a manufacturer or importer shall review statements and data in the TDB. If the substance is not listed in TDB, the manufacturer or importer shall review all standard reference works and relevant NIOSH documents specified in paragraph (b)(1) of this Appendix. A determination that a substance or mixture does not pose a particular Category B hazard may not be based upon data or statements discovered through this initial review. However, a positive determination that a substance or mixture poses a particular Category B hazard may be based upon statements or data discovered through this review, without further evaluation for that hazard. If a manufacturer or importer chooses not to base a positive hazard determination upon data or statements in the TDB, standard reference works, and NIOSH documents then to determine whether a substance or mixture poses the particular Category B hazard in question, the manufacturer or importer shall:

(i) Review unpublished studies or data subject to the manufacturer's or importer's custody or control, or the custody or control of the manufacturer's or importer's employees, agents, and contractors; and

(ii) Conduct a literature search, including available back files, utilizing the following four (4) computerized files or commercial on-line files containing at least the equivalent information: Medline[®], Toxline[®], Cancerlit[®], and RTECS.

For further information on the data files cited contact: National Library of Medicine, 8600 Rockville Pike, Bethesda, Maryland 20209, Telephone: (301) 496-6193.

Data Files:

Medline[®]: This data base contains references to biomedical journal articles published in the current, as well as the two (2) preceding years. Medline[®] can also be used to update a search periodically. Coverage of previous periods (back to 1966) is provided by back files. An English abstract, if available, is frequently included.

Toxline[®]: (Toxicology Information Online) contains a collection of references published since 1976 together with earlier references concerning mutagens and teratogens. Coverage of previous periods (in some cases, antedating 1966) is provided by Toxback. Almost all references have abstracts or indexing terms.

Cancerlit[®]: A large data file concerned with various aspects of cancer. All references have English abstracts.

RTECS: (Registry of Toxic Effects of Chemical Substances, formerly the Toxic Substances List) is a compilation prepared by the National Institute for Occupational Safety and Health (NIOSH). There is no back file. RTECS contains acute and chronic toxicity data.

(2) *Search Parameters.* The literature search shall:

Use CAS number, chemical name, generic name, trade name and brand name to identify the toxicologic and epidemiologic literature for the substance. Additional search parameters may be specified by a manufacturer or importer, as necessary, to expedite the search performance.

(3) *Search Output.* The material identified in the literature search shall be obtained and used for hazard determinations by the party performing the evaluation, under the following conditions:

(i) In the case of material published entirely in English (including material with a foreign language summary), all such material shall be evaluated.

(ii) In the case of material published entirely in a foreign language (including material with an English summary), such material shall be evaluated only if:

(A) The material is available for review by the manufacturer or importer as part of the National Library of Medicine inter-library loan program or any other inter-library loan program; and

(B) An English version of the summary indicates the possible existence of a regulated hazard not documented in the English literature.

(iii) Notwithstanding paragraphs (1) and (2), the manufacturer or importer has actual knowledge of the content of the foreign language material.

(4) Relevant unpublished studies and data, and relevant studies or data disclosed by a literature search, shall be evaluated as required by Appendix B.

(5) A review of unpublished studies and data, and a review of the materials covered by a literature search may not disclose evidence which meets the evaluative criteria of Appendix B demonstrating whether the substance or mixture poses the Category B hazard in question. In such cases, if the initial review of the TDB, or standard reference works and relevant NIOSH documents, disclosed or cited to relevant data or studies, these data or studies shall be evaluated as required by Appendix B.

(d) *Updating.* Following the initial evaluation of any substance or mixture for all Category A and Category B hazards, a manufacturer or importer shall remain current with the scientific

literature in a manner generally accepted by the scientific community.

Appendix B—Evaluation of Scientific Materials Relating to Category B Hazards

This Appendix describes how relevant unpublished data and studies and relevant material disclosed by a literature search is to be evaluated in determining whether a substance or mixture poses a Category B hazard. This Appendix is applicable both to evaluation of evidence concerning substances and mixtures as a whole. Substances regulated by 29 CFR Part 1910, Subpart Z are deemed to be hazardous without the need for an independent evaluation but must be evaluated to determine the particular hazard they pose.

(a) Definitions

(1) "Adequate and well-controlled study" means a study whose design and presentation incorporate principles that have been developed and recognized by the scientific community as essential to the production of valid scientific conclusions. A study which incorporates the following principles shall be considered "adequate and well-controlled" for the purpose(s) of this section:

(i) *Study subjects (Cases):* Study subjects shall constitute a representative sample from the source population. In the case of cross-sectional studies (see paragraph (3)(i) of this subsection of this Appendix) the study and comparison population are the same. This means that:

(1) The extent to which the study subjects represent the population from which they are drawn is documented.

(2) Although random selection of study cases is preferred, a systematic selection process which minimizes bias is acceptable.

(3) Selection and exclusion criteria are documented.

(ii) *Comparison subjects (Controls):* Comparison subjects shall constitute a representative sample from an appropriate comparison population. The term "appropriate comparison population" shall include populations used in studies utilizing matching techniques. This means that:

(1) The extent to which the comparison subjects represent the population from which they are drawn is documented.

(2) Although random selection of comparison cases is preferred, a systematic selection process which minimizes bias is acceptable. Where appropriate, an historical control is suitable for establishing that a substance or mixture is hazardous.

(3) The appropriateness of the control population is addressed.

(iii) *Data Collection.* The methods of data collection shall be fully described. This means that:

(1) The risk factors, including degree of exposure, are characterized.

(2) The diagnostic criteria for the health conditions are indicated.

(3) The steps taken to minimize observer bias in data collection—e.g., double-blind evaluation techniques, are documented.

(4) The potential sample biasing effect of differential response rates in study and comparison subjects is considered, where the situation arises.

(iv) *Analytic methods.* The analytic methods shall be identified precisely. This means that:

(1) Where differential response rates occur between study and comparison subjects, the method used to compensate for this differential is identified;

(2) Steps taken to identify observer bias are described;

(3) The use of appropriate methods to control confounding, e.g., matching or statistical techniques, such as blocking or covariance analysis, are documented; and

(4) The various quantifiers of hypothesis testing, e.g., Type I and II error probabilities and one-tailed versus two-tailed tests, are specified.

(v) *Documentation.* The study shall provide sufficient documentation of results so as to permit adequate peer review.

(vi) *Animal studies.* In the case of paragraph (gg)(22)(xvii) of this regulation, other acute or chronic adverse health effects, the animal effects must be generally accepted as a model for the indicated human health effects.

(vii) Regardless of paragraphs (i)–(vi) of this definition of "adequate and well-controlled," a study shall be considered "adequate and well-controlled" for the purposes of this section if the study has been published in a peer-reviewed journal in which the articles are published entirely in English (except for a foreign language summary), or the conclusions of the study have been substantially endorsed in standard reference works or NIOSH documents or material identified in the literature search (See Appendix A) or in other published material, by at least one (1) other independent qualified expert.

(2) "Case report" means, for the purposes of this section, a statistically uncontrolled report involving two or more cases which asserts a cause and effect relationship between exposure to a substance or mixture and the

subsequent occurrence of adverse effects. At a minimum, to be acceptable for further evaluation under this Appendix, a "case report" must describe, at least qualitatively, the level and duration of exposure and specify the diagnostic criteria for the morbid condition described.

(3) "Epidemiological study" means a study employing one of the following sample designs:

(i) "Cross-sectional design" in which an evaluation is made of the differential prevalence of disease where individuals are classified by level of exposure and relevant characteristics and where neither disease nor exposure is selected for;

(ii) "Case-control design" in which an evaluation is made of the differential exposure to a substance or mixture for individuals who are initially selected according to the presence or absence of a specific disease or injury and relevant variables.

(iii) "Cohort design" in which an evaluation is made of the differential incidence of disease among two or more groups, the individuals of which are classified by level of exposure to a specific agent and relevant characteristics, each group being free of the outcome variable at the outset and followed over some period of time.

For purposes of this section, the term "cohort design" shall include "proportional mortality studies" in which the percent distribution of causes of death of a group exposed to a hazardous material is compared with that of an appropriate control group.

(4) "Peer-review" journal means a scientific journal which routinely distributes articles submitted for publication to one or more qualified experts whose judgment as to the quality of an article, including the appropriateness of its conclusions, is an important determinant in the journal's decision whether to publish the article.

(5) "Qualified expert" means a person who, because of his or her education, training, experience or a combination of these factors, is capable of evaluating and interpreting data on the hazards associated with exposure to, or of contact with, a substance or mixture.

(6) "Statistically significant" means a Type I error of 0.10 or less (significance level of 10 percent or less) for the particular statistic used for significance testing. The Type I error level may be based upon a one-or-two tailed significance test, at the investigator's discretion. In uncommon circumstances, the determination of a probability level in a particular study may be informal, e.g., the uniform occurrence of a tumor

following exposure which would otherwise be rarely encountered.

(b) *Ascertaining Hazardous Materials.* A substance or mixture shall be classified as a Category B hazard under paragraph (1) by an importer or manufacturer, if one or more of the following reports is found:

(1) A single adequate and well-controlled epidemiologic study demonstrates a statistically significant association between exposure to the substance or mixture and a covered hazard, and the conclusion that the hazard is the result of the exposure, in whole or in part, is accepted by any subgroup of experts qualified in epidemiology, biostatistics, clinical pharmacology or human genetics; or

(2) A single adequate and well-controlled laboratory experiment involving domestic or experimental mammals demonstrates a statistically significant relationship between exposure to the substance or mixture and a covered hazard, where the exposure is through routes of administration other than cavity instillation or implantation in any organ system and the conclusion that the hazard is the result of the exposure, in whole or in part, is accepted by a subgroup of experts qualified in biostatistics, pharmacology, physiology, toxicology or genetics; or

(3) Case-reports involving a total of more than two individuals strongly suggest the conclusion that there is a cause and effect relationship, in whole or in part, between exposure to the substance or mixture and the subsequent occurrence of a covered hazard and the conclusion that such a relationship exists is accepted by a subgroup of experts qualified in the relevant scientific discipline.

(c) *Resolving a Material's Status Where Data or Analyses Are Inconsistent.*

In determining whether a substance or mixture is a Category B hazard, the following rules of data construction for evaluating studies shall apply:

(1) When comparing studies of the same type (human or animal) which yield conflicting results, the importer or manufacturer shall consider a substance or mixture as hazardous if a subgroup of qualified experts, considering the available studies, would conclude that the substance or mixture is hazardous. Studies which yield differing estimates of disease, all of which are greater than zero, shall not be considered in conflict;

(2) When considering inconsistent studies of different types (human and animal), the importer or manufacturer shall rely upon human data if the human

data indicate a greater hazard than the animal data.

(3) The importer or manufacturer may rely upon human data if such data indicate a lesser hazard in humans than in animals, provided that the group of exposed human subjects was large enough for an increase in hazard incidence or prevalence (whichever statistic was used in the study) of 25% above that in controls not exposed to that substance to have been detected 80% of the time and the studies meet the criteria of subsection (a) of this Appendix. However, negative case reports in humans, i.e., no hazard on exposure, usually will not negate positive animal data.

(4) Where alternative analytic statistical techniques produce inconsistent results in terms of statistical significance, the study shall be considered to demonstrate statistical significance, provided that the alternative techniques demonstrating significance is acceptable to a subgroup of experts qualified in epidemiologic or toxicologic study methods.

(5) An importer or manufacturer may conclude that a mixture does not present the same hazards as a hazardous constituent substance, provided that the group of animal or human subjects exposed to the mixture was large enough so that an increase in hazard incidence or prevalence equal to that established for the substance or 25% above that in unexposed controls, whichever is the lesser, would have been detected 80% of the time and the studies meet the criteria of subsection (a) of this Appendix.

(d) *Creation of a Rebuttable Presumption by Expert Opinion.* The determination that a subgroup of qualified experts accepts the conclusions of a study may be evidenced by informal memos, correspondence, evaluation or reference to published material such as the references, handbooks or NIOSH materials (See Appendix A). When the conclusions of a study have been substantially endorsed by at least one qualified independent expert, i.e.; an expert not an author of the original study or a collaborator of any of the authors at the time of the endorsement, the conclusions of the study shall be rebuttably presumed to be acceptable to a subgroup of qualified experts, in the absence of strong evidence to the contrary.

(e) *Delabeling.* A determination by an importer or manufacturer that a substance or mixture is hazardous may be withdrawn by that importer or manufacturer if:

(1) Subsequent to the hazard determination, the methodology of the study or studies upon which the hazard determination is based are found to be critically flawed or inappropriate, i.e., the association originally observed is subsequently shown to be due to sample bias, observer bias or a confounding variable; or

(2) The availability of a negative adequate and well-controlled study or studies results in a revision of the opinion of qualified experts such that no subgroup of experts, considering all the relevant evidence, accepts the association or relationship between exposure to the substance or mixture and the covered hazard.

Appendix C—Hazard Warnings Information

Introduction

This APPENDIX specifies the hazard warnings for hazardous substances and mixtures. In using this APPENDIX, the following rules apply in communicating hazard warnings for mixtures:

1. Hazard warnings must appear for hazardous mixtures.

2. Hazard warnings must appear for hazardous constituent substances of a mixture where such substances pose hazards for which the mixture as a whole was not evaluated.

3. The priority of hazard warnings as set out in this Appendix is not affected by whether a hazard attaches to a mixture as a whole, or to one of its constituent substances.

(a) *Label Elements for Hazardous Warnings—Summary of Requirements.*

A hazard warning must include the following elements:

(1) Signal word, as prescribed in paragraph (b)(1) of this Appendix;

(2) The word POISON and the skull and crossbones symbol for highly toxic materials, as prescribed in paragraph (b)(2) of this Appendix;

(3) Statement of hazards, as prescribed in paragraph (b)(3) of this Appendix;

(4) Precautionary statements, as prescribed in paragraph (b)(4) of this Appendix;

(5) Additional labels elements, if appropriate, or specified in subsection (c) of this Appendix.

(6) Hazard warning elements (1)–(3) must be cross-referenced to the CAS number and common name of the substance or common name of the mixture producing the hazard.

(7) In the event that precautionary statements or additional label elements are contradictory in the case of mixture, the manufacturer or importer shall

resolve the contradiction using sound scientific judgment.

(b) *Label Elements—Description.*

(1) *Signal Word.* If a substance or mixture has more than one hazard a hazard warning label shall include only the signal word (DANGER!, WARNING!, OR CAUTION!) that corresponds to the category of its most severe hazard.

(2) *The Word POISON and the Skull and Crossbones Symbol.* A hazard warning for a highly toxic material must include the word POISON and the skull and crossbones symbol. On a hazard warning label, the word POISON and the symbol, in any color, must appear on a background of distinctly contrasting color. The symbol must appear in immediate proximity to the word POISON. Use the word POISON and the symbol, in addition to, and not in place of, the signal word DANGER!

(3) *Statement of Hazards.* A hazard warning label must include the statement of hazards prescribed in Table 1 for Category A hazards and Table 2 for Category B hazards for the appropriate hazard class. If the hazard may have a delayed onset, the hazard warning shall also indicate this. Subsection (d) of this APPENDIX lists examples of useful statements of hazard which may be used in addition to those mandated by Tables 1 and 2 of this APPENDIX. If a substance or mixture has more than one hazard, its hazard warning must include a statement of hazard of each hazard. If a substance or mixture has more than one hazard, statements of hazard for which the signal word "DANGER!" is required, together with the signal word, must precede statements of hazard for which the signal word "WARNING!" or "CAUTION!" is required, and statements of hazard for which the signal word "WARNING!" is required together with the signal word, must precede statements of hazard for which the signal word "CAUTION!" is required.

(4) *Precautionary Statements.* A hazard warning must describe appropriate precautionary measures (such as "Keep away from heat, sparks, or open flames" or "Wear rubber gloves") to avoid injury as a substance or mixture is used in the workplace. If a substance or mixture has more than one hazard, its hazard warning must include appropriate precautionary statements for each hazard. If precautionary statements can be combined for different classes of hazards, eliminate any redundant phrases.

Table 1.—Hazard warning statements for Category A hazards

Class of hazard	Signal word	Statement of hazard
Corrosive:		
Eye	Danger	Corrosive: Causes severe eye burns.
Eye and skin	do	Corrosive: Causes severe eye and skin burns.
Dangerously reactive material:		
Explosive	do	Explosive.
Water-reactive	do	Dangerous when wet: Reacts violently with water.
Organic peroxide	do	May form explosive organic peroxides.
Extremely flammable liquid.	do	Extremely flammable.
Pyrophoric material	do	Extremely flammable: Catches fire if exposed to air.
Strong oxidizer	do	Strong oxidizer: Contact with other material may cause fire.
Flammable material	Warning	Flammable.
Pressure-generating material.	do	May generate dangerous pressure.
Compressed gas	Caution	Contents under pressure.
Combustible liquid	do	Combustible.

Table 2.—Hazard warning statements for Category B hazards

Class of hazard	Signal word	Statement of hazard
Toxic:		
By inhalation	Warning	Toxic: May be fatal if inhaled.
By absorption	do	Toxic: May be fatal if absorbed through skin.
By ingestion	do	Toxic: May be fatal if swallowed.
Highly toxic:		
By inhalation	Danger!	Highly toxic: Fatal if inhaled.
By absorption	Poison.	Highly toxic: Fatal if absorbed through skin.
By ingestion	do	Highly toxic: Fatal if swallowed.
Endangers human life.	do	Highly toxic: May be fatal if inhaled, absorbed, or swallowed.
Carcinogens	Danger	May cause (optional): Organ/system cancer.
Reproductive toxins	do	May cause birth defects. May cause reproductive problems.
Irritant:		
Eye	Warning	Irritant: Causes eye irritation.
Eye and skin	do	Irritant: Causes eye and skin irritation.
Lung	do	Irritant: Causes lung (chest) irritation.
Sensitizer:		
Lungs	do	Sensitizer: Causes respiratory reaction.
Skin	do	Sensitizer: Causes allergic skin reaction.
Other adverse health effects.		Exposure may cause (specify disease(s), sign(s) or symptom(s)).
Includes mental or behavior alterations.	Warning	Or may cause acute or chronic health effects.

(c) *Additional Label Elements.*

(1) A hazard warning or other listing must include the following elements, if they are appropriate:

(i) Antidotes, as prescribed in paragraph (2); or
(ii) Instructions in case of fire, spill, or leak, as prescribed in paragraph (3).

(iii) Instructions for container handling and storage, as prescribed in paragraph (4).

(2) *Antidotes.* If there is any appropriate antidote that is generally available and may be administered by a layman, the hazard warning must include it.

(3) *Instructions in Case of Fire, Spill, or Leak.* If there are any special instructions for confining and extinguishing fires and for cleaning up spills or leaks, the hazard warning must include them.

(4) *Instructions for Container Handling and Storage.* If there are any special instructions for container handling and storage, the hazard warning must include them.

(5) *Optional Additional Information.* A hazard warning may include additional hazard warning information that is not required by this Part, provided that the additional information does not contradict or detract from the required information. Terms such as "safe," "non-toxic," or "harmless" must not be used on a hazard warning.

(d) *Useful Phrases for Category A and Category B Hazard Warnings.*

This subsection of the APPENDIX contains a listing of additional warning phrases that a manufacturer or importer of a hazardous substance or mixture may use together with the required hazard warning. The Agency is providing this subsection of this APPENDIX simply as a listing of useful warning phrases. OSHA does not require that a manufacturer or importer of a hazardous substance or mixture use any of these additional phrases with a hazard warning.

(a) *Statements of Hazard.*

(1) *Liberates Gas.* Liberates Poisonous Gas. Fire Liberates Poisonous Gas. Contact With Acid Liberates Poisonous Gas. Contact With Water or Acid Liberates Poisonous and Flammable Hydrogen Sulfide Gas.

Spills Liberates Dangerous Gas. Contact With Water or Moist Air Liberates Irritating Gas. Liberates Heavy Gas Which May Cause Suffocation.

(2) *Fire Hazard.* Contact With Water May Cause Flash Fire. May Catch Fire if Allowed To Become Damp. Spills May Cause Fire. Heat, Shock, or Contact With Other Materials May Cause Fire. Contact With Other Materials May Cause Fire, Especially if Heated Reacts Violently With Water to Liberate and Ignite Hydrogen Gas. Powerful Oxidizer.

May Form Flammable Dust-Air
Mixtures.

(3) *Explosive.* Heat, Shock, or Contact
With Other Materials May Cause
Explosion.

Contact With Other Materials May
Cause Explosion, Especially If Heated.

May Form Explosive Peroxides. Forms
Shock-Sensitive Mixtures With Certain
Other Materials. May Explode if Water
Content is 10 percent or Below.

(4) *Pressure Hazard.* Contamination
May Result in Buildup of Dangerous
Pressure. Liquid (GAS) (VAPOR) Under
Pressure. Extremely Hazardous Liquid
(GAS) (VAPOR) Under Pressure.

(5) *Miscellaneous.* Cannot Be Made
Nonpoisonous.

[FR Doc. 81-1564 Filed 1-13-81; 1:02 p.m.]

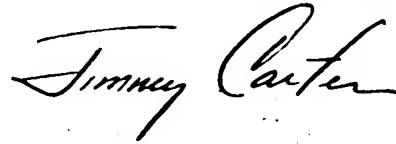
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Presidential Documents

Executive Order 12223 of June 30, 1980

Occupational Safety and Health Programs for Federal Employees

By the authority vested in me as President by the Constitution and statutes of the United States of America, including Section 7902(c) of Title 5 of the United States Code, and in accord with Section 19 of the Occupational Safety and Health Act of 1970, as amended (29 U.S.C. 668), and in order to provide sufficient time for the development of adequate implementing instructions which will govern the new occupational safety and health programs for Federal employees, Section 1-704 of Executive Order No. 12196 of February 26, 1980, is hereby amended to read, "This Order is effective October 1, 1980."



THE WHITE HOUSE,
June 30, 1980.

[FR Doc. 80-20100
Filed 7-1-80; 10:31 am]
Billing code 3195-01-M

alveolar/bronchiolar adenomas were observed in female mice at a statistically significant incidence when compared to controls, but the incidence appeared to be possibly related to the presence of a dipropyl nitrosamine contaminant. *N*-nitroso-di-n-propylamine (NDPA) was found in the trifluralin used in the test at concentrations of 84-88 ppm.

A preliminary report of a recently submitted chronic toxicity/oncogenicity study shows an increase in tumors of the urinary tract in male and female rats treated with trifluralin. However, the theoretical maximum residue contribution (TMRC) from the proposed use is only 2×10^{-5} mg/day/1.5 kg daily diet. This minute increase is considered negligible in comparison with the current estimated TMRC of 0.0429 mg/day/1.5 kg daily diet. In addition, the proposed use does not change the percentage of the acceptable daily intake (ADI) contributed by currently existing tolerances.

The ADI for trifluralin is calculated to be 0.1 mg/kg of body weight (bw)/day with regard to chronic effects other than oncogenicity and based on the NOEL of 400 ppm in the 3 long-term dog feeding studies and using a 100 fold safety factor. The maximum permitted intake (MPI) for a 60 kg person is calculated to be 6 mg/day. Tolerances have previously been established for a variety of commodities, including the crop grouping "leafy vegetables," and range from 0.05 ppm to 2.0 ppm. These tolerances utilize 0.72 percent of the ADI.

On August 30, 1979, the agency published in the Federal Register (44 FR 50911) a notice of determination and availability of a position document concerning trifluralin. After extensive review, the agency determined that the benefits outweighed the risks for all uses if the formulated products contained less than 1 ppm of NDPA. However, the agency will re-evaluate all the existing tolerances for trifluralin when the final report and validation audit of the laboratory records on all the chronic toxicity/oncogenicity studies are available.

Based on the above information considered by the agency and the insignificance of upland cress in the diet, it is concluded that the tolerance of 0.05 ppm in or on upland cress would protect the public health. In light of the chronic toxicity/oncogenicity studies, the agency considers the cancer risk from dietary exposure of trifluralin-treated upland cress to be insignificant (negligible) since the ADI and TMRC are not affected by the proposed use, since upland cress can be substituted in the

diet for other leafy vegetables for which a tolerance currently exist. Therefore, 40 CFR Part 180 is amended as set forth below.

Any person adversely affected by this regulation may, on or before January 30, 1981, file written objections with the Hearing Clerk, EPA, Rm. M-3708 (A-110), 401 M. St., SW., Washington, D.C. 20460. Such objections should be submitted in triplicate and specify the provisions of the regulation deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. If a hearing is granted, the objections must be supported by grounds legally sufficient to justify the relief sought.

Note.—Under Executive Order 12044, EPA is required to judge whether a regulation is "significant" and therefore subject to the procedural requirements of the Order or whether it may follow other specialized development procedures. EPA labels these other regulations "specialized." This regulation has been reviewed, and it has been determined that it is a specialized regulation not subject to the procedural requirements of Executive Order 12044.

Effective date: December 31, 1980.

(Sec. 406(e), 66 Stat. 514 (21 U.S.C. 346a(e)))

Dated: December 18, 1980.

Robert V. Brown,
Acting Deputy Assistant Administrator for Pesticide Programs.

Therefore, Subpart C of 40 CFR Part 180 is amended by alphabetically inserting "upland cress" in the table under § 180.207 to read as follows:

§ 180.207 Trifluralin; tolerances for residues.

Commodity	Parts per million
Upland Cress	0.05

[FR Doc. 80-40648 Filed 12-30-80; 8:45 am]
 BILLING CODE 6560-32-M

GENERAL SERVICES ADMINISTRATION

41 CFR Part 101-20

[FPMR Amendment D-78]

Federal Property Management Regulations; Management of Buildings and Grounds; Accident and Fire Prevention Standards

AGENCY: General Services
 Administration.

ACTION: Final rule.

SUMMARY: The General Services Administration (GSA) is amending its regulations to update certain provisions of the accident and fire prevention standards. The proposed changes require that GSA ensure that space is consistent with Occupational Safety and Health Act (OSHA) standards, provide a procedure for processing reports of hazardous conditions, and for resolving conflicting complaints that result from safety and health inspections by GSA and occupant agency inspection personnel.

EFFECTIVE DATE: December 31, 1980.

FOR FURTHER INFORMATION CONTACT:
 Mr. Craig Schilder, Chief, Safety Management Branch, Accident and Fire Prevention Division (202-566-0961).

SUPPLEMENTARY INFORMATION: The General Services Administration has determined that this regulation will not impose unnecessary burdens on the economy or on individuals and, therefore, is not significant for the purposes of Executive Order 12044.

1. The table of contents for Part 101-20 is amended to recaption and revise two entries and add one entry, as follows:

- 101-20.109-3 Responsibilities of agencies.
- 101-20.109-11 Accident prevention and fire protection activities of occupant agencies.
- 101-20.109-12 Correction of hazardous conditions.

Subpart 101-20.1—Building Operations, Maintenance, Protection, and Alterations.

2. Section 101-20.109-1 is revised to read as follows:

§ 101-20.109-1 Policy.

It is the policy of GSA that:
 (a) Standards for space will equal those promulgated under the Occupational Safety and Health Act (OSHA) of 1970 (Public Law 91-596); Executive Order 12196; and 29 CFR 1960, Subpart C—Agency Occupational Safety and Health Standards.

(b) The safety and health of occupants and visitors will not be endangered by exposure to unnecessary risks and intolerable conditions.

(c) Safeguards will be provided to allow emergency forces to accomplish their missions without undue danger of entrapment.

(d) Fire-protection and other safety features will be provided to minimize exposure to the community to unnecessary risks or undue danger.

(e) Safeguards that minimize personal harm, property damage, or impairment

of GSA or agency operations will be provided according to the level of risk which includes the number of persons involved, the value of the property, and the importance of the Federal activity.

3. Section 101-20.109-3 is recaptioned and revised to read as follows:

§ 101-20.109-3 Responsibilities of agencies.

Accidents involving personal injury or property damage to buildings and grounds for which GSA is responsible will be reported immediately to the appropriate GSA buildings manager. Each occupant agency shall ensure that:

(a) Operations and activities and their use in GSA-assigned space conform to the policies of § 101-20.109-1;

(b) All reasonable precautions are taken to avoid accidental injuries, work related illnesses, fires, and property damage; and

(c) A safety, health, and fire protection liaison is appointed with full authority and responsibility to represent the occupant agency management with the GSA buildings manager.

4. Section 101-20.109-11 is amended by revising its caption and paragraph (a) to read as follows:

§ 101-20.109-11 Accident prevention and fire protection activities of occupant agencies.

(a) Periodic inspections, in accordance with Executive Order 12196 and 29 CFR 1960, are required to be conducted by the occupant agency for its operations and activities to include their assigned space within GSA buildings or grounds. All substandard building conditions shall be documented and a copy of the documentation shall be provided to the GSA buildings manager not later than 10 workdays after identification of the substandard condition. These inspections do not relieve GSA of its responsibilities for these areas, nor do inspections by GSA or others relieve occupant agencies of their responsibilities for maintaining full knowledge of conditions.

5. Section 101-20.109-12 is added to read as follows:

§ 101-20.109-12 Correction of hazardous conditions.

(a) Conditions within the occupant agency's responsibility to correct, which affect GSA buildings and grounds and could affect any GSA employees or other agency employees in the performance of their responsibilities, shall be corrected within 30 workdays in accordance with 20 CFR 1960 or established occupant agency program requirements, whichever is more

restrictive. An abatement plan shall be prepared when corrective actions require more than 30 calendar days. This plan shall contain an explanation of why the corrections are delayed, a proposed timetable for the abatement, and a summary of steps being taken in the interim to protect GSA and other agency personnel from injury or illness and GSA buildings and grounds from damage by the unsafe or unhealthy working condition. The occupant agency's liaison shall send a copy of the hazard correction plan to the GSA buildings manager. (Usually this plan will be the same as required by 29 CFR 1960). If the abatement will take more than 60 workdays, a copy of the plan shall also be provided by the GSA buildings manager to the appropriate GSA regional Accident and Fire Prevention Branch. Occupant agencies may correct hazardous conditions in accordance with FPMR 101-20.105, which establishes authority for agencies to procure special alteration services of not more than \$1,000.

(b) Conditions considered to be within the scope of GSA's responsibility to correct which are identified in occupant agency's assigned space, shall be forwarded to the GSA buildings manager for action. The resolution steps are:

- (1) Identification;
- (2) Documentation;
- (3) Presentation;
- (4) Investigation;
- (5) Determination; and
- (6) Resolution.

(c) To correct a condition considered to be within the scope of GSA's responsibility, six basic steps shall be taken: The occupant agency shall identify, document, and present the problem to the GSA buildings manager, after which GSA will investigate, determine, and resolve the problem. Identification of these conditions may be by an occupant agency employee or by an occupant agency safety and health and fire protection specialist.

When an imminently dangerous situation exists, as defined by 29 CFR 1960.28, a telephone call from the occupant agency's liaison to the GSA buildings manager shall constitute the occupant agency's identification, documentation, and presentation of the problem to GSA. Otherwise, a report shall document the hazardous condition and cite references to specific OSHA standards violated. Documentation should include inspection reports, photographs, sketches or drawings for a safety problem, and an industrial hygiene survey report for health problems. The OSHA Form No. 7 (complaint) may be used as part of the

documentation. The occupant agency's liaison shall determine that there are reasonable grounds to believe that an unsafe or unhealthful condition exists before presenting the situation to the GSA buildings manager.

(d) GSA action:

(1) Upon a documented agency request, GSA will investigate reports of unsafe or unhealthful conditions. This investigation, when requiring an on-site inspection, shall be completed within 24 hours for imminent danger situations, 20 working days for potentially serious conditions, and 20 working days for other safety and health conditions.

(2) The GSA buildings manager will determine a plan of action to resolve the problems and inform the agency within 5 working days after the investigation.

(3) Whenever possible, GSA shall resolve the condition within 20 working days after determining the plan of action and shall inform the agency when resolution has been completed.

(4) When resolution will take longer than 30 working days, the GSA buildings manager shall prepare and submit to the occupant agency liaison an abatement plan.

(5) GSA shall give priority in the allocation of resources for prompt abatement of conditions.

(6) The abatement plan shall set forth a timetable for abatement and a summary of interim steps to protect employees. The plan shall include the: Location of the hazard, hazard assessment (probability of occurrence and potential severity), discussion of the hazard, corrective action to be taken, specific reference to OSHA standard(s) violated, justification for deferring corrective action, proposed timetable, interim corrective action, and the appropriate management signature.

(d) Actions by the buildings manager or other regional management personnel that do not resolve the problem to the satisfaction of the occupant agency's management may be formally presented to the appropriate GSA Regional Administrator by the occupant agency's regional, district, or equivalent management.

(e) Unsatisfactory resolutions by GSA regional management may be formally presented to the Administrator of GSA, Washington, DC 20405, by the agency head or an authorized designee.

(f) Hazardous conditions observed in other than the occupant agency's assigned space should be brought to the attention of the responsible agency's occupant liaison for required action.

(Sec. 205(c), 63 Stat. 390; 40 U.S.C. 486(c))

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